U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4541–4560

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation; (2) criminal proceedings which were terminated with a plea or verdict of guilty; and (3) injunction proceedings terminated with the entry of an injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms or individuals* charged to be responsible for violations.

Similar actions with respect to products alleged to be in violation while held for sale after shipment in interstate commerce are reported in other supplements.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 30, 1955.*

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*For presence of a habit-forming narcotic without warning statement, see No. 4542; omission of, or unsatisfactory, ingredients statements, No. 4541; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4541, 4542; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4541, 4542.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4541–4560

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501 (c), the strength of the article differed from that which it purported and was represented to possess; and, Section 501 (d) (2), a substance had been substituted in whole or in part for the article.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4541. Alpha-estradiol tablets. (F. D. C. No. 33749. S. No. 23–101 L.)

INFORMATION FILED: 1–21–53, S. Dist. N. Y., against Cedardale Drug Co., Inc., New York, N. Y., and Sol Lederman, president and treasurer.

SHIPPED: 4–4–50, from New York to New Jersey.

CHARGE: 502 (b) (1) and (2)—the tablets failed to bear a label when shipped containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the tablets failed to bear a label containing the common or usual name of each active ingredient; and, 502 (f) (1)—the labeling of the tablets failed to bear adequate directions for use.

PLEA: Not guilty.

DISPOSITION: On 8–16–54, the case came on for trial before the court without a jury, and at the conclusion of the trial the court rendered a verdict of guilty. On 9–21–54, the court fined each defendant $1,000.

4542. Pentobarbital sodium capsules. (F. D. C. No. 34854. S. Nos. 2–193/5 L.)

INFORMATION FILED: 7–22–53, E. Dist. Va., against Cradock Pharmacy, Inc., Cradock, Va.

SHIPPED: Between 12–17–51 and 1–3–52, from Virginia to Florida.

CHARGE: 502 (b) (1) and (2)—the article failed to bear a label when shipped containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (d)—the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and, 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

*See also No. 4560.

PLEA: Guilty.

DISPOSITION: 11–16–53. $900 fine.

4543. B-amino-complex tablets. (F. D. C. No. 35676. S. No. 45–682 L.)

QUANTITY: 98 100-tablet btls. at Cambridge, Mass.

SHIPPED: 9–15–53 and 9–24–53, from New York, N. Y., by Unitone Corp.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label described in notice of judgment No. 4549.

LIBELED: 10–1–53, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use for the purpose for which it was intended, namely, in the treatment of deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 10–29–53 directing the removal of the libel action to the Eastern District of New York. On 2–1–55, with the consent of the claimant, Unitone Corp., a decree of condemnation and destruction was entered.

4544. Polyzone device. (F. D. C. No. 36465. S. No. 69–747 L.)

QUANTITY: 1 device at Pueblo, Colo.

SHIPPED: 6–16–53, from Los Angeles, Calif., by the Polyzone Co.

ACCOMPANYING LABELING: Leaflet entitled "For Doctors Only Polyzone."

RESULTS OF INVESTIGATION: The article was assumed to consist of a device for transforming ordinary diatomic oxygen into ozone (triatomic oxygen) for administration to the human body.

LIBELED: 3–26–54, Dist. Colo.

CHARGE: 502 (a)—the accompanying labeling of the device when shipped contained false and misleading representations that ozone produced by the device was nontoxic and that the device provided, through the agency of the ozone generated by it, an adequate and effective treatment for rheumatism, sciatica, heel spurs, arthritis, male and female pelvic infections, vaginal infections, rectal inflammations, infected rectal crypts, rectal tumors, rectal fissures, colitis, hemorrhoids, fistulas, pruritus ani, spastic sphincters, inflammations of the eye, ear, nose, and throat, sinus infections, internal and external ulcerations, and all acute and chronic conditions; and, 502 (f) (1)—the labeling of the device failed to bear adequate directions for use.

DISPOSITION: 11–4–54. Default—delivered to Food and Drug Administration.

4545. Polyzone device. (Inj. No. 284.)

COMPLAINT FOR INJUNCTION FILED: 10–22–54, S. Dist. Calif., against Roy G. Collison, t/a Polyzone Co., Los Angeles, Calif.

ACCOMPANYING LABELING: A leaflet entitled "For Doctors Only Polyzone" and a booklet entitled "Polyzone Therapy Manual."

RESULTS OF INVESTIGATION: The device was designed to produce ozone by the passage of oxygen through an electrical field.

CHARGE: That the defendant was causing the introduction into interstate commerce of the *Polyzone device*, which was misbranded under 502 (a) by reason of false and misleading representations, namely:

(1) That the ozone produced by the device was beneficial and useful for all acute and chronic conditions, arthritis, catarrhal deafness, fistulas,

fungus in the ear, fungi infections, generalized itching, heel spurs, hemorrhoids, indigestion, mixed infections, otitis media, painful tooth sockets following dental surgery, pneumonia, poison ivy, poison oak, pruritus ani, pruritus vulvae, rectal fissures, rectal tumors, rheumatism, sciatica, sore throat, spastic sphincters, stomach ulcers, trench mouth, tuberculosis, deep burrowing ulcers, internal and external ulcerations, urticaria, uterine fibroids, wounds; for disorders, infections, and inflammations of the bladder, cervix, colon, ear, eustachian tubes, eyes, gallbladder, gums, intestines, liver, male and female pelvis, mouth, nerves, nose, pharynx, prostate, rectum, rectal crypts, sinuses, skin, system generally, throat, tonsils, urethra, vagina, and vulva; and for inclusion in a test for tubal patency; whereas such ozone or any other ozone was not beneficial or useful for such conditions and purposes, or for any therapeutic or diagnostic purpose;

(2) That the ozone produced by the device was nontoxic, whereas it was capable of producing toxicity when administered to the human body;

(3) That the ozone produced by the device was nonirritating to normal body tissues, whereas it was capable of causing irritation to body tissues which were normal or abnormal; and,

(4) That the ozone produced by the device was suitable for use in the treatment of sinusitis, rhinitis, otitis media, running ears, sore throat, trench mouth, tonsilitis, gum infection, painful tooth sockets, poison oak, ulcers, wounds, cryptitis, colitis, pneumonia, urethral and bladder irritations, prostate trouble, and in a test for tubal patency, whereas the labeling failed to reveal the fact, which was material in the light of such representations, that ozone was contraindicated for such conditions and purposes.

The device was alleged also to be misbranded under 502 (f) (1) in that its labeling failed to bear adequate directions for use.

Disposition: 10–22–54. The defendant having consented, the court entered a decree permanently enjoining the defendant against the introduction into interstate commerce of the *Polyzone device* or any other ozone generating device when misbranded as alleged in the complaint.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4546. Mephenesin tablets and phenobarbital tablets. (F. D. C. No. 36838. S. Nos. 40–073 L, 40–075 L.)

Quantity: 4 1,000-tablet btls. of *mephenesin tablets* and 24 1,000-tablet btls. of *phenobarbital tablets* at Las Vegas, Nev.

Shipped: 1–2–54 and 2–17–54, from Van Nuys, Calif., by W. L. Palmer.

Label in Part: (Btl.) "Tablets 3–D Brand Mephenesin Antispasmodic Muscular Relaxant Each Tablet Contains 0.5 Gram" and "Tablets Phenobarbital U. S. P. 1½ Grain (0.097 G. M. S.)."

Results of Investigation: Analyses showed that the *mephenesin tablets* contained 77.8 percent of the labeled amount of mephenesin; that the *phenobarbital tablets* contained 82.3 percent of the labeled amount of phenobarbital; and that the disintegration time of the *phenobarbital tablets* exceeded the United States Pharmacopeia maximum allowable time by 38 percent.

Libeled: 6–18–54, Dist. Nev.

Charge: *Mephenesin tablets.* 501 (c)—the strength of the tablets when shipped differed from that which they purported and were represented to possess, namely, 0.5 gram of mephenesin per tablet; and, 502 (a)—the label statement "Mephenesin * * * Each Tablet Contains 0.5 Gram" was false and misleading.

Phenobarbital tablets. 501 (b)—the strength of the tablets when shipped differed from, and their quality fell below, the standard set forth in the United States Pharmacopeia for phenobarbital tablets since the tablets contained less than 94 percent of the declared amount of phenobarbital, the minimum permitted by the standard, and the disintegration time of the tablets exceeded the maximum allowable time of the standard by 38 percent; and, 502 (a)—the label statement "Tablets Phenobarbital U. S. P. 1½ Grain (0.097 G. M. S.)" was false and misleading as applied to the tablets, which failed to meet the requirements of the United States Pharmacopeia for phenobarbital tablets.

DISPOSITION: 8–6–54. Default—destruction.

4547. Alpha-tocopherol and alpha-tocopheryl acetate. (F. D. C. No. 33341. S. Nos. 22–859/60 L.)

QUANTITY: 29 btls. of *alpha-tocopherol* and 29 btls of *alpha-tocopheryl acetate* at New York, N. Y.

SHIPPED: 6–7–51, from Bloomfield, N. J., by Pharmaceutical Co. of New Jersey.

LABEL IN PART: (Btl.) "100 Grams Alpha Tocopherol Nepera (Vitamin E) U. S. P." and "100 Grams Alpha Tocopherol Nepera (Vitamin E) U. S. P. Acetate."

LIBELED: On or about 7–16–52, S. Dist. N. Y.

CHARGE: 501 (d) (2)—when shipped, products essentially devoid of alpha-tocopherol and alpha-tocopheryl acetate, respectively, had been substituted for *alpha-tocopherol* and *alpha-tocopheryl acetate*, respectively; and, 502 (a)—the label statements "Alpha Tocopherol" and "Alpha Tocopherol * * * Acetate" were false and misleading.

DISPOSITION: 4–7–55. Default—destruction.

4548. Alpha-tocopheryl acetate. (F. D. C. No. 33340. S. No. 22–855 L.)

QUANTITY: 20 btls. at New York, N. Y.

SHIPPED: 6–18–51, from Bloomfield, N. J., by Pharmaceutical Co. of New Jersey.

LABEL IN PART: (Btl.) "Darrylle Chemical Co. 121 Broad St. New York 4, N. Y. 500 Grams Alpha Tocopheryl Acetate (Vitamin E Acetate)."

LIBELED: On or about 7–16–52, S. Dist. N. Y.

CHARGE: 501 (d) (2)—when shipped, a product esentially devoid of alpha-tocopheryl acetate had been substituted for *alpha-tocopheryl acetate;* and, 502 (a)—the label statement "Alpha Tocopheryl Acetate" was false and misleading.

DISPOSITION: 4–7–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4549. B-amino-complex tablets. (F. D. C. No. 30384. S. No. 77–448 K.)

QUANTITY: 21 100-tablet btls. at Peoria, Ill.

SHIPPED: 12–8–50, from New York, N. Y., by Barrows Chemical Co.

*See also Nos. 4544–4548.

LABEL IN PART: "B-Amino-Complex * * * Daily dose of 6 tablets contains: Vitamins Vitamin B_1 (Thiamine Hydrochloride) 18.0 mg. Vitamin B_2 (Riboflavin) 27.0 mg. Niacinamide 180.0 mg. Vitamin B_6 (Pyridoxine Hydrochloride) 3.0 mg. High Potency Yeast 200.0 mg. Brewer's Type Yeast 200.0 mg. Inositol 60.0 mg. Choline Hydrochloride 60.0 mg. Panthenol (Equal to Cal. Pantothenate 30 mg.) 26.1 mg. Amino Acids (Vitagenic Accelerators) as contained in Yeast Protein Enzymatic Hydrolysate 1.0 Gm. fortified with Nucleic acid 100.0 mg. Glutamic Acid 50.0 mg. Glycine 50.0 mg. Cysteine Hydrochloride 35.0 mg. Di and Tri-Valent Minerals Iron (Ferric Citro Pyrophosphate Soluble) 28.8 mg. Copper (copper sulfate) 2.1 mg. Magnesium (magnesium sulfate) 5.9 mg. Zinc (zinc sulfate) 1.4 mg. Cobalt (cobalt sulfate) 1.3 mg."

ACCOMPANYING LABELING: Leaflets entitled "Amazing New Medical Discovery" and placards bearing a picture of the head of a woman and the words "Amazing Discovery Checks Deafness Helps Restore Hearing Clinically Tested Come in for Free Booklet."

LIBELED: 1–25–51, S. Dist. Ill.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained statements which represented that the article was an adequate and effective treatment for deafness, whereas the article was not an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 3–20–51 directing the removal of the libel action to the Eastern District of New York. On 7–11–51, the Unitone Corp., New York, N. Y., as claimant, filed an answer to the libel. Thereafter, interrogatories were served upon and answered by each party. An order to compel the claimant to make further answers to the interrogatories was entered on 3–16–54, and was complied with by the claimant. On 2–4–55, with the consent of the claimant, a decree of condemnation and destruction was entered.

4550. B-amino-complex tablets. (F. D. C. No. 35696. S. No. 59–473 L.)

QUANTITY: 34 100-tablet btls. at Atlanta, Ga.

SHIPPED: 4–7–52, from New York, N. Y., by Sherman Foods, Inc.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label previously described in notice of judgment No. 4549.

ACCOMPANYING LABELING: Circulars entitled "A Revolutionary Advance in Nutrition Now B-Amino-Complex instead of B-Complex."

LIBELED: 10–7–53, N. Dist. Ga.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 11–25–53 directing the removal of the libel action to the Eastern District of New York. On 2–1–55, with the consent of the claimant, Unitone Corp., New York, N. Y., a decree of condemnation and destruction was entered.

4551. B-amino-complex tablets. (F. D. C. No. 35697. S. No. 55–913 L.)

QUANTITY: 5 100-tablet btls. at Pittsburgh, Pa.

SHIPPED: 3–13–53, from New York, N. Y., by Balanced Foods, Inc.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label previously described in notice of judgment No. 4549.

ACCOMPANYING LABELING: Folders entitled "Amazing New Medical Discovery Checks Deafness."

LIBELED: 10–8–53, W. Dist. Pa.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 10–29–53 directing the removal of the libel action to the Eastern District of New York. On 2–1–55, with the consent of the claimant, Unitone Corp., New York, N. Y., a decree of condemnation and destruction was entered.

4552. B-amino-complex tablets. (F. D. C. No. 36021. S. No. 39–555 L.)

QUANTITY: 642 100-tablet btls. at Los Angeles, Calif.

SHIPPED: (Tablets and the folders described below) 4–1–53 and 7–27–53, from New York, N. Y., by Unitone Corp. and (circulars described below) on or about 10–2–53, from New York, N. Y., by Universal Nutritions, Inc.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label previously described in notice of judgment No. 4549.

ACCOMPANYING LABELING: Folders entitled "Amazing New Medical Discovery Checks Deafness" and circulars entitled "Health and Nutrition News Fall 1953."

LIBELED: 10–16–53, S. Dist. Calif.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 12–10–53 directing the removal of the libel action to the Eastern District of New York. On 2–1–55, with the consent of the claimant, Unitone Corp., a decree of condemnation and destruction was entered.

4553. B-amino-complex tablets. (F. D. C. No. 36026. S. Nos. 64–724/5 L.)

QUANTITY: 68 100-tablet btls. at Seattle, Wash.

SHIPPED: 9–1–53 and 9–22–53, from New York, N. Y., by Universal Nutritions, Inc.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label previously described in notice of judgment No. 4549.

ACCOMPANYING LABELING: Folders entitled "Amazing New Medical Discovery Checks Deafness" and circulars entitled "Health and Nutrition News Fall 1953."

LIBELED: 10–29–53, W. Dist. Wash.

CHARGE: 502(a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 3–1–54 directing the removal of the libel action to the Eastern District of New York. On 2–1–55, with the consent of the claimant, Unitone Corp., New York, N. Y., a decree of condemnation and destruction was entered.

4554. B-amino-complex tablets. (F. D. C. No. 36101. S. No. 79-096 L.)

QUANTITY: 48 100-tablet btls. at Cleveland, Ohio.

SHIPPED: 6-15-53 and 6-25-53, from New York, N. Y., by Sherman Foods, Inc.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label previously described in notice of judgment No. 4549.

ACCOMPANYING LABELING: Leaflets entitled "Amazing New Medical Discovery Checks Deafness" and booklets entitled "The Nutritional Guide."

LIBELED: 11-4-53, N. Dist. Ohio.

CHARGE: 502(a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered directing the removal of the libel action to the Eastern District of New York. On 2-1-55, with the consent of the claimant, Unitone Corp., New York, N. Y., a decree of condemnation and destruction was entered.

4555. B-amino-complex tablets. (F. D. C. No. 36160. S. No. 65-381 L.)

QUANTITY: 83 100-tablet btls. at Des Moines, Iowa.

SHIPPED: (Tablets) 7-27-53, 8-10-53, and 9-30-53, from New York, N. Y., by Universal Nutritions, Inc., and from Chicago, Ill., by Health Food Jobbers, Inc.; (folders described below) during November 1951, from Springfield, Mass., by Universal Nutritions; and (leaflets described below) within last 5 years from Chicago, Ill., by Health Food Jobbers, Inc.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label previously described in notice of judgment No. 4549.

ACCOMPANYING LABELING: Folders designated "Nutrition Topics" and leaflets designated "Amazing New Medical Discovery Checks Deafness."

LIBELED: 11-30-53, S. Dist. Iowa.

CHARGE: 502(a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 1-9-54 directing the removal of the libel action to the Eastern District of New York. On 2-1-55, with the consent of the claimants, Unitone Corp., New York, N. Y., and Universal Nutritions, Inc., a decree of condemnation and destruction was entered.

4556. St. Roke's Climatex. (F. D. C. No. 36842. S. No. 82-650 L.)

QUANTITY: 6 btls. at Erie, Pa.

SHIPPED: 3-5-54, from Portland, Oreg., by St. Roke Co.

LABEL IN PART: (Btl.) "Contents: 90 Caplets St. Roke's Climatex Each Caplet Contains: Vitamin B_1 (Thiamin Hydrochloride) Vitamin C (Ascorbic Acid) Vitamin E (d,Alpha Tocopherol Acetate) Iron (Ferrous Gluconate) Plus Excipients * * * Directions: For the relief of functionally-caused change of life (menopause) symptoms."

ACCOMPANYING LABELING: Pamphlets designated "Change of Life" and display placards designated "Now! For Relief of Change Of Life * * * St. Roke's Climatex."

LIBELED: 6-15-54, W. Dist. Pa.

CHARGE: 502(a)—when the article was shipped, its bottle label and accompanying labeling contained false and misleading representations that the article was effective in "change of life," glandular imbalance, hot flashes, sweats, nervousness, difficult breathing, dizziness, crying spells, restless sleep, palpitation, headaches, and backaches, when symptomatic of the menopause.

DISPOSITION: 7–19–54. Default—destruction.

4557. Pine needle bath oil. (F. D. C. No. 36495. S. No. 19–856 L.)

QUANTITY: 136 combination packages, each containing 1 2-oz. btl. and 1 6-oz. btl., at St. Paul, Minn.

SHIPPED: 2–26–54, from Buffalo, N. Y., by The House Of Pine.

LABEL IN PART: (Btl.) "Balpine"; (paper band joining 1 2-oz. btl. and 1 6-oz. btl.) "Balpine Concentrated Pine Needle Bath Oil Induces Sleep Eases Nerves Trial * * * Offer * * * This is the same Balpine used by physicians and health sanitoriums in the treatment of various skin, nerve, muscular, and circulatory disorders. * * * Balpine is a special blend of imported Swiss and Tyrolean pine oils."

LIBELED: 4–10–54, Dist. Minn.

CHARGE: 502 (a)—when the article was shipped, its labeling, namely, the paper band joining a 2-oz. btl. and a 6-oz. btl., contained false and misleading representations that the article was effective in the treatment of skin, nerve, muscular, and circulatory disorders; that it would induce sound sleep; and that it would relieve tenderness and ease nerves.

DISPOSITION: 6–23–54. Default—destruction.

4558. Uranium ore. (F. D. C. No. 36547. S. No. 57–959 L.)

QUANTITY: 5 bags at Baltimore, Md.

SHIPPED: 1–19–54, from Picacho, Ariz., by Fred R. Brown.

ACCOMPANYING LABELING: Pamphlet entitled "Uranium Center Tombstone Arizona * * * The Health Center of the Southwest."

RESULTS OF INVESTIGATION: Examination showed that each bag consisted of a leather, pillow-like bag 16 inches long, 16 inches wide, and 1½ inches thick containing crushed ore, which emitted beta and gamma radiation at the level of approximately 4 mr per day. This was less radiation than emitted from the radium dial of an ordinary wrist watch.

LIBELED: On or about 5–5–54, Dist. Md.

CHARGE: 502 (a)—when the article was shipped, its accompanying labeling contained false and misleading representations that the article provided an adequate and effective treatment for the relief of asthma, arthritis, calcium stiffened joints, rheumatism, bursitis, and sinus disorders.

DISPOSITION: 6–2–54. Default—delivered to the Food and Drug Administration.

4559. Heel-Ins device. (Inj. No. 268.)

COMPLAINT FOR INJUNCTION FILED: 10–6–53, Dist. Vt., against Heel-Ins, Inc., St. Albans, Vt., Katharine Smith, president of the corporation, and Paula Laddey, secretary-treasurer.

CHARGE: That the defendants had been introducing into interstate commerce a device called *Heel-Ins* consisting of a pair of metal plates, one of copper and the other of zinc, which device was misbranded under 502 (a) by reason of false and misleading statements in its labeling.

The complaint alleged that the device was shipped in a folder entitled "Here are your HEEL-INS"; that the folder contained instructions to place the plates on the inner soles of a pair of shoes, one in each shoe, and bore the statement "Designed for the relief of arthritis"; and that such statement was false and misleading since the device was not effective for the relief of arthritis.

DISPOSITION: On 11–2–53, the court, after hearing the arguments of counsel, refused to issue a temporary injunction. Thereafter, an answer to the complaint was filed by the defendants, and a set of interrogatories was filed by the government and was answered by the defendants.

On 6–23–54, with the consent of the defendants, a decree was entered enjoining the defendants, during the pendency of the action and until its final determination, from introducing the device into interstate commerce so long as it was misbranded. The prohibited misbranding was that which involved labeling which represented the device to be beneficial, effective, or have value in the cure, mitigation, treatment, or prevention of arthritis, or which was false and misleading in any particular. In addition, the decree specifically prohibited the use of the above-mentioned folder as labeling.

DRUGS FOR VETERINARY USE

4560. Lions stock remedy. (F. D. C. No. 36831. S. No. 88–875 L.)

QUANTITY: 6 33⅓-lb. drums and 12 125-lb. drums at Centreville, Mich.

SHIPPED: 3–30–54, from St. Louis, Mo., by Live Stock Remedy Co.

LABEL IN PART: (Drum) "Lions Stock Remedy * * * Directions Inside Worm Seed Mandrake Iron Magnesium & Sodium Sulfate Gentian Ginger Anise Seed Sassafras Blood Root Sulphur Sodium Bi Carb Licorice Senna Asafoetide Potassium Iodide."

ACCOMPANYING LABELING: Circular designated "Lions Stock Remedy Made Since 1888 Directions."

LIBELED: 6–9–54, W. Dist. Mich.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for white scours of pigs and calves and for restoring shoats to a normal, healthy condition; and, 502 (f) (1)—the labeling failed to bear adequate directions for use since the labeling recommended use of the article for hogs, cows, cattle, horses, sheep, dogs, cats, poultry, turkeys, and chicks, but failed to state the conditions or purposes for which the article was intended to be given to such animals.

DISPOSITION: 7–15–54. Consent—claimed by Live Stock Remedy Co. and relabeled.

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PRODUCTS

[1] (4541) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4541) Prosecution contested.
[2] (4545, 4559) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4561–4580

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which were adulterated or misbranded within the meaning of the Act while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation and (2) criminal proceedings which were terminated with pleas of guilty or nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms or individuals* charged to be responsible for violations.

Similar actions with respect to products alleged to be in violation at the time of shipment are reported in other supplements.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 19, 1956.*

CONTENTS*

*For presence of a habit-forming narcotic without warning statement, see No. 4565; omission of, or unsatisfactory, ingredients statements, Nos. 4564, 4565; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4564–4566; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4564.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4561–4580

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; and, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin and it was from a batch with respect to which a certificate issued pursuant to Section 507 was not effective; and, Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4561. Sodium ascorbate injection. (F. D. C. No. 37011. S. Nos. 90–433/4 L.)

QUANTITY: 299 25-ampul cartons, 10 6-ampul cartons, and 497 individual ampuls at Kansas City, Mo., in possession of B. F. Ascher & Co., Inc.

SHIPPED: Between 11–28–52 and 6–1–54, a number of unlabeled ampuls in bulk were shipped from Decatur, Ill., and Seymour, Ind.

LABEL IN PART: (Carton) "10 cc. Sodium Ascorbate Injection * * * 10 cc. contain: Sodium Ascorbate equivalent to Ascorbic Acid 1 Gram [or "2 Grams"] * * * For Intramuscular or Intravenous Injection Manufactured for B. F. Ascher & Company, Inc."

ACCOMPANYING LABELING: Pamphlets designated "physician's report."

RESULTS OF INVESTIGATION: After receipt of the article at Kansas City, it was labeled as described above by the consignee, B. F. Ascher & Co., Inc. The above-mentioned pamphlets were printed locally for the consignee.

LIBELED: 7–16–54, W. Dist. Mo.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for the treatment of poliomyelitis, mumps, herpes Zoster, chickenpox, influenza, virus pneumonia, and virus encephalitis; for the prevention and treatment of

measles; and for the prevention of recurrence of herpes simplex; and, 505 (a)—the article was a new drug since it was not generally recognized among qualified experts as safe for use in the treatment and prevention of the above-mentioned conditions, and that as a new drug it could not be lawfully introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–19–54. Consent—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4562. Procaine penicillin G in aqueous suspension. (F. D. C. No. 36894. S. No. 76–703 L.)

QUANTITY: 108 100-carton boxes and 90 loose cartons at Canton, Mass.

SHIPPED: 10–2–53 and 10–5–53, from Terre Haute, Ind.

LIBELED: 7–13–54, Dist. Mass.

CHARGE: 502 (l)—while held for sale, the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin, and it was from a batch with respect to which a certificate issued pursuant to the law was not effective since the effective date of the original certificate had expired and an application for an extension of the effective date of the original certificate was denied.

DISPOSITION: 11–26–54. Default—destruction.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4563. Monkey Brand Gland Compound. (F. D. C. No. 36868. S. Nos. 79–316/7 L.)

QUANTITY: 2 drums containing a total of 199,750 tablets in bulk, together with a number of 30-tablet bottles in retail cartons at Columbus, Ohio, in possession of Gold's, Inc.

SHIPPED: The tablets had been shipped in bulk drums on 5–6–52 and 5–17–54, from Baltimore, Md.

LABEL IN PART: (Retail carton) "Now in Tablet Form Original Monkey Brand Gland Compound The Original Gland Tonic * * * Sole Distributors Gold's, Inc. Columbus, O."; (btl.) "Monkey Brand Compound Tablets * * * Contains Vitamin B_1, Iron Carbonate, Nux Vomica, Zinc Phosphide, Cascarin and Damiana."

ACCOMPANYING LABELING: Circulars entitled "Monkey Brand Compound Tablets."

RESULTS OF INVESTIGATION: Upon receipt of the bulk shipments of the tablets, the consignee, Gold's, Inc., repackaged the tablets into bottles and cartons labeled as described above. The bottle labels and cartons, together with the above-mentioned circulars, were obtained by the consignee from local printers.

LIBELED: 6–30–54, S. Dist. Ohio; libel amended on or about 7–21–54.

CHARGE: 502 (a)—the labeling of the article, while it was held for sale, namely, the carton and bottle labels and the above-mentioned circulars, contained false and misleading representations that the article was effective for enriching the blood, toning up the nervous force, revitalizing persons with a tired, worn-out, old age feeling and lack of ambition, and those who suffer from loss of sleep, impaired appetite, and nervousness; restoring sufferers to health,

strength, and happiness; assisting the vital organs in performing their function of providing health and youthful vigor; increasing strength and endurance; causing a general feeling of renewed life; overcoming general weakness, backache, pains in the joints, and invigorating vital organs; bringing the flush of health to the face of weak and rundown men and women; assisting the organs of the body in performing their functions; providing abundant power, life force, and the needed health and energy to aid nature in warding off disease; overcoming the effects of weakened kidneys; preventing rheumatism, lumbago, weak back, pimples, and headaches; treating gastric and intestinal disturbances, indigestion, and nervous stomach; rejuvenating one who is rundown and has a completely worn-out system; building vitality, enabling one to feel years younger; and restoring youthful vigor, pep, and strength; and, 503 (b) (4)—the article was a drug subject to 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–7–54. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4564. (F. D. C. No. 33722. S. Nos. 23–551 L, 23–554 L.)

INFORMATION FILED: 5–14–53, S. Dist. N. Y., against Henry H. Schumann, t/a Schumann's Drug Store, Hunter, N. Y.

CHARGE: Between 8–1–51 and 8–4–51, *tablets containing a mixture of sulfadiazine and sulfamerazine* and *tablets containing a mixture of crystalline penicillin potassium G, sulfamerazine, sulfadiazine, and sulfacetamide* were each dispensed once without a prescription. Such act of dispensing resulted in the drugs being misbranded as follows: 502 (b) (2)—the drugs failed to bear labels containing an accurate statement of the quantity of contents; 502 (e) (2)—the labels of the drugs failed to bear the common or usual name of each active ingredient; and, 502 (f) (1) and (2)—the labeling of the drugs failed to bear adequate directions for use and adequate warnings against use. The *tablets containing a mixture of sulfadiazine and sulfamerazine* were also misbranded under 502 (b) (1) because they failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

PLEA: Guilty.

DISPOSITION: 10–4–54. Fine, $50; $25 remitted.

4565. (F. D. C. No. 34322. S. Nos. 14–804/7 L, 14–809/11 L.)

INFORMATION FILED: 4–13–53, Dist. Kans., against Self Service Drugs, a partnership, Hutchinson, Kans., Marvin W. Gates, manager of the partnership, and Earl R. Hanna and Frank Sewell, pharmacists.

CHARGE: Between 3–26–52 and 4–10–52, *dextro-amphetamine sulfate tablets* were dispensed 4 times (counts 1, 2, 3, and 4) and *Mebaral tablets* were dispensed 3 times (counts 5, 6, and 7) without a prescription. Such dispensing resulted in the drugs being misbranded as follows: 502 (b) (2)—the drugs failed to bear labels containing an accurate statement of the quantity of contents; and, 502 (f) (1)—the labeling of the drugs failed to bear adequate directions for use.

The drugs were further misbranded as follows: 502 (e) (2)—the label of the *dextro-amphetamine sulfate tablets* failed to bear the common or usual

name of each active ingredient; and, 502 (d)—the *Mebaral tablets* contained a chemical derivative of barbituric acid, and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

PLEA: Nolo contendere, by partnership to counts 1, 2, 3, 4, and 5; by Gates to counts 1, 2, 3, and 4; by Hanna to counts 1, 3, 4, 6, and 7; and by Sewell to counts 2 and 5.

DISPOSITION: 6–23–53—court fined partnership $175, Gates $100, and Sewell $50, and assessed costs against each defendant. 10–12–54—Hanna fined $50.

4566. Sulfanilamide. (F. D. C. No. 37360. S. No. 8–506 L.)

QUANTITY: 1 12-lb. drum and 12 1-lb. bags at Herkimer, N. Y., in possession of Kean's Cut Rate Drugs.

SHIPPED: 3–9–54, from Rahway, N. J.

RESULTS OF INVESTIGATION: The article was shipped in a bulk drum, and, upon receipt by the consignee, a portion of the article was repackaged into 1-lb. bags and relabeled.

LIBELED: 11–13–54, N. Dist. N. Y.

CHARGE: 502 (f) (1)—the labeling of the article (bulk and repackaged material) while held for sale failed to bear adequate directions for use, and the article was not entitled to any exemption from such requirement; and, 502 (b) (2)—the article in the bags failed to bear a label containing an accurate statement of the quantity of contents.

DISPOSITION: 1–11–55. Default—destruction.

4567. Pruvo tablets. (F. D. C. No. 35265. S. Nos. 55–127 L, 55–137 L.)

QUANTITY: 1 drum containing 20,000 tablets, and 432 btls., 75 tablets each, at Milwaukee, Wis., in possession of Pruvo Pharmacal Co.

SHIPPED: 5–13–53, from Cleveland, Ohio.

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce in bulk, and, upon receipt by the consignee, a number of the tablets were repacked into bottles. Advertisements recommending *Pruvo tablets* for the treatment of arthritis and rheumatism were printed in local newspapers on the instructions of, and from mats furnished by, the Pruvo Pharmacal Co.

LIBELED: 5–20–53; amended 9–30–53, E. Dist. Wis.

CHARGE: 502 (f) (1)—the labeling of the article (in bulk and as repackaged) while held for sale to bear adequate directions for use by reason of the failure to list arthritis and rheumatism, which were the diseases for which the drug was intended and for which it was offered; and, the labeling failed also to bear adequate directions for use for the purposes for which it was intended, namely, as an effective treatment for all forms or arthritis and rheumatism, red, swollen, inflamed joints due to arthritis, and the crippling effect resulting therefrom.

DISPOSITION: 3–18–55. The Pruvo Pharmacal Co., claimant, having filed an answer and later having consented to the entry of a decree, the court ordered that the product be condemned and destroyed.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4568. Juniper berries. (F. D. C. No. 37284. S. No. 68–649 L.)

QUANTITY: 30 130-lb. bags at New York, N. Y.

SHIPPED: Prior to 12–28–53, from Italy.

LIBELED: 10–6–54, S. Dist. N. Y.

CHARGE: 501 (a) (1)—contained insects while held for sale.

DISPOSITION: 10–29–54. Consent—claimed by Karl H. Landes & E. Balint, Inc., New York, N. Y. Segregated, 8 lbs. destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4569. Dextro-amphetamine sulfate tablets. (F. D. C. No. 37377. S. No. 72–605 L.)

QUANTITY: 197 100-tablet btls. at Baltimore, Md.

SHIPPED: 1–27–54, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 76 percent of the declared amount of dextro-amphetamine sulfate.

LIBELED: On or about 11–23–54, Dist. Md.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it purported and was represented to possess, namely, 5 milligrams of d-amphetamine sulfate per tablet; and, 502 (a)—the label statement "Each Tablet Contains: * * * d-Amphetamine Sulfate . . . 5 mg." was false and misleading.

DISPOSITION: 12–15–54. Default—destruction.

4570. Lixerin. (F. D. C. No. 36850. S. No. 45–850 L.)

QUANTITY: 1,203 8-oz. btls. at Bridgeport, Conn.

SHIPPED: Between 2–28–52 and 7–21–52, from Worcester, Mass.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 75 percent of the declared amount of vitamin B_{12}.

LIBELED: 7–6–54, Dist. Conn.

CHARGE: 501 (c)—while the article was held for sale, its strength differed from that which it purported and was represented to possess, namely, 20 micrograms of vitamin B_{12} per fluid ounce; and, 502 (a)—the label statement "Each fluid-ounce contains: * * * Vitamin B–12 . . . 20 mcg." was false and misleading.

The libel alleged also that three other products, namely, Tobenex capsules, Heminal tablets, and Aronnol capsules, were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 9–14–54. Default—delivery to a charitable institution for its use and not for sale.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4571. Homeopathic drugs. (F. D. C. No. 37291. S. No. 88–894 L.)

QUANTITY: The following amounts of *homeopathic drugs* at Milwaukee, Wis., in possession of Louis Pauly: 7 1-oz. btls., 77 2-oz. btls., and 15 1-lb btls. of "E & K Homoeopathic Tablet Triturates Calcium Fluoride (or Calcarea Fluorica) 6x"; 115 2-oz. btls., 3 4-oz. btls., and 6 1-lb. btls. of "E & K Homoeopathic Tablet Triturates Calcium Fluoride (or Calcarea Fluorica) 12x"; 31 1-oz. btls., 8 2-oz. btls., and 28 1-lb. btls. of "E & K Homoeopathic Tablet Triturate Calcium Phosphate (or Calcarea Phosphorica) 6x"; 27 2-oz. btls. and 15 1-lb. btls. of "E & K Tablets Triturates Homoeopathic Calcium Sulfate (or Calcarea Sulphurica) 6x"; 1 1-lb. btl. of "E & K Homoeopathic Triturates Ferrum Phosphoricum (Iron Phosphate) 1x"; 14 1-oz. btls., 26 2-oz. btls., and 35 1-lb. btls. of "E & K Homoeopathic Triturates Ferrum Phosphate (or Ferrum Phosphoricum) 6x"; 115 2-oz. btls., 4 4-oz. btls., and 2 1-lb. btls. of "E & K Homoeopathic Tablet Triturates Ferrum Phosphate (or Ferrum Phosphoricum) 12x"; 2 1-lb. btls. of "Homoeopathic Trituration of 2x Ferrum Phosphate"; 1 1-lb. btl. of "Homoeopathic Trituration of Ferrum Phosphate 1x"; 15 1-oz. btls., 38 2-oz. btls., 33 1-lb. btls., and 2 1-lb. cartons of "E & K Homoeopathic Tablet Triturate Kali Muriaticum (Potassium Chloride) 6x"; 1 1-lb. btl. of "E & K Homoeopathic Tablet Triturates Kali Phosphate 1x"; 11 1-oz. btls., 200 2-oz. btls., and 19 1-lb. btls. of "E & K Homoeopathic Tablet Triturate Kali Phosphoricum (Potassium Chloride) 3x"; 64 2-oz. btls. and 17 1-lb. btls. of "E & K Homoeopathic Tablet Triturates Kali Sulfate (or Kali Sulphuricum) 6x"; 2 1-lb. btls. of "E & K Homoeopathic Tablet Triturates Magnesium Phosphate 1x"; 73 1-oz. btls., 47 2-oz. btls., and 42 1-lb. btls. of "E & K Homoeopathic Tablets Triturates Magnesium Phosphate (or Magnesium Phosphoricum) 3x"; 21 2-oz. btls. and 32 1-lb. btls. of "E & K Homoeopathic Triturates Natrum Muriate (or Natrum Muriaticum) 3x"; 12 1-oz. btls. of "E & K Tablet Triturates Homoeopathic Natrum Muriate 6x"; 24 2-oz. btls. and 24 1-lb. btls. of "E & K Homeopathic Tablet Triturate Naturm Phosphoricum (Sodium Phosphate) 3x"; 18 1-oz. btls., 4 2-oz. btls., and 6 1-lb. btls. of "E & K Homoeopathic Tablet Triturates Natrum Phosphate (or Natrum Phosphoricum) 6x"; 91 1-oz. btls., 95 2-oz. btls., and 17 1-lb. btls. of "E & K Tablet Triturates Homoeopathic Natrum Sulfate (or Natrum Sulphuricum) 6x"; 1 1-lb. carton of "E & K Homoeopathic Tablet Triturate Silicea (Silica) 3x"; 8 1-oz. btls., 156 2-oz. btls., and 32 1-lb. btls. of "E & K Homoeopathic Tablet Triturates Silicea 6x"; 111 2-oz. btls., 3 4-oz. btls., and 14 1-lb. btls. of "E & K Homoeopathic Tablet Triturates Silicea 12x"; 8 1-lb. btls. of "Special Formula Tablets * * * pink Each Tablet Contains: * * * Parts Calcium phosphate * * * Calcium fluoride * * * Calcium sulfate * * * Ferrum phosphate * * * Silicea * * * Kali Muriate * * * Kali phosphate * * * Kali sulfate * * * Natrum Muriate * * * Natrum phosphate * * * Natrum sulfate"; 37 2-oz. btls. and 11 1-lb. btls. of "E & K Tablet Triturates Homoeopathic Calcarea Fluor. 6x Ferrum Phos. 6x Kali Muriate 6x Silicea 6x Equal parts"; 2 1-lb. btls. of "Special Formula Homoeopathic Trituration * * * Ferrum Phos 6x . 3 Parts Kali Mur 6x . 3 Parts Natrum Mur 6x . 3 Parts Kali Sulf 6x . 1 Part"; 100 2-oz. btls. and 13 1-lb. btls. of "E & K Tablet Triturates Homoeopathic Ferrum Phos.

*See also Nos. 4561, 4563, 4569, 4570.

6x Kali Phos. 3x Magnesium Phos. 3x Equal parts"; 21 1-lb. btls. of "E & K Tablet Triturates Homoeopathic Ferrum Phos. 6x 3 parts Kali Phos. 3x 3 parts Magnesium Phos. 3x 3 parts Kali Muriate 6x 1 part"; 38 2-oz. btls. and 8 1-lb. btls. of "Special Formula Tablets (or E & K Tablet Triturates Homoeopathic) Yellow Ferrum Phos. 6x 2 parts Natrum Mur. 6x 2 parts Kali Sulf. 6x 1 part (parts not shown on 2-ounce size)"; 21 1-lb. btls. of "E & K Tablet Triturates Homoeopathic Kali Phos. 3x Mag. Phos. 3x Silicea 6x"; 38 2-oz. btls. and 3 1-lb. btls. of "E & K 5 in 1 Spec. Compound Tablets Homoeopathic Natrum Mur 3x Natrum Phos 3x Natrum Sulf 3x Equal Parts of Each Silicea 6x 60% Calc. Fluor 6x 40%"; 9 2-oz. btls. and 3 1-lb. btls. of "Special Formula Tablets * * * Each Tablet Contains: Natrum Phos 6x Natrum Sulf 6x Calcarea Fluor 6x Kali Mur 6x Ferrum Phos 6x Equal Parts of Each"; 60 2-oz. btls. and 3 1-lb. btls. of "Special Formula Tablets * * * Size mold 5 Red. 7 in 1 Each Tablet Contains: Natrum Phos 6x Natrum Sulf 3x Calcarea Fluor 3x Kali Mur 3x Ferrum Phos 6x Kali Sulf 6x Silicea 6x Equal Parts of Each"; 22 2-oz. btls. and 10 1-lb. btls. of "E & K Tablet Triturates Homoeopathic Silicea 6x 60 per cent Cal. Fluor. 6x 40 per cent"; and 47 2-oz. btls. and 14 1-lb. btls. of "E & K Tablet Triturates Homoeopathic Silicea 6x 2 parts Fer. Phos. 6x 3 parts Kali Sulf. 6x 1 part Colored Green."

SHIPPED: On various dates during 1953 and 1954, from Chicago, Ill.

ACCOMPANYING LABELING: Booklets entitled "What the Forgotten 12 Tissue Remedies * * *," "Supplement Letter No. 6 June 1945," "Supplement Letter No. 15 November 1949," "Supplement Letter No. 19 April 1952," and "Letter No. 22 January 1954," and leaflets entitled "Letter No. 13 * * * September 1948," "Excerpts From My Coming Letter No. 14 For 1949," "January 1954 Supplement Letter No. 21A," "Mr. Roy C. Frank * * * January 1953," "Supplement Letter No. 20 January 1953," and "Supplement Letter No. 21."

RESULTS OF INVESTIGATION: The above-mentioned booklets and leaflets were printed in the Milwaukee area for the consignee.

LIBELED: 10–25–54, E. Dist. Wis.

CHARGE: 502 (a)—The accompanying labeling of the articles while held for sale contained false and misleading representations that the articles constituted adequate and effective treatments for tuberculosis, dermatitis, bronchitis, infantile paralysis (polio), fungus infections, chronic diseases, itching, eczema, prostatic hypertrophy, skin rashes, sores, all skin diseases, pyorrhea, arthritis, Hodgkin's disease, piles, boils, asthma, constipation, headaches, epilepsy, earache, tumors, pneumonia, abcess of the rectum, coughs, colds, psoriasis, acne, anemia, bed wetting, carbuncles, dyspepsia, impetigo, nervousness, fever, insomnia, neuritis, paralysis, prostate trouble, sinus diseases, stys on the eyes, fistula, high and low blood pressure, menopausal symptoms, leg cramps, lymphoblastoma, cancer, leukemia, Buerger's disease, colitis, nervous and mental breakdown, gallbladder trouble, glandular affections, female tumors, sciatica, diabetes, rheumatism, jungle rot, tonsillitis, appendicitis, breast cancer, shingles, multiple sclerosis, warts, ulcers, Bright's disease, heart trouble, gallstones, hay fever, other allergic diseases, muscular dystrophy, virus infections, mumps, and stomach ulcers.

DISPOSITION: 12–7–54. Default—destruction.

4572. Tryptacin tablets. (F. D. C. No. 34636. S. No. 34–852 L.)

QUANTITY: 16 cases, 3 doz. btls. each, at St. Louis, Mo., in possession of Katz Drug Co.

SHIPPED: 12–16–52, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "Tryptacin * * * Tablets * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

ACCOMPANYING LABELING: Copies of an advertisement which had appeared in a St. Louis newspaper on 1–7–53.

RESULTS OF INVESTIGATION: The above-mentioned copies of the newspaper advertisement were on display in the store and in the store window of the Katz Drug Co. The advertisement had been printed on the instruction of that company.

LIBELED: 2–3–53, E. Dist. Mo.

CHARGE: 502 (a)—the accompanying labeling of the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers, inflamed, irritated, and painful stomach walls, and indigestion.

DISPOSITION: 4–9–54. Consent—claimed by Rhodes Pharmacal Co., Inc., Cleveland, Ohio, and relabeled.

4573. Arthban tablets. (F. D. C. No. 36879. S. No. 88–859 L.)

QUANTITY: 1 drum containing 20,000 tablets in bulk and 19 100-tablet boxes at Green Bay, Wis.

SHIPPED: 2–1–54, from Buffalo, N. Y.

LABEL IN PART: (Box) "Arthban * * * Tablets Active Ingredients: Calcium Succinate Gr. ½ Acetylsalicyclic Acid Gr. 5 Ascorbic Acid 20 M. G. * * * Sole Distributors Beneficial Home Products Co. 811 Klaus St. Green Bay, Wisconsin."

ACCOMPANYING LABELING: Leaflets entitled "Arthban Banish Arthritis Pains" and a number of loose box labels.

RESULTS OF INVESTIGATION: The interstate shipment described above consisted of 1 drum of 25,500 tablets in bulk, and, upon the receipt of the shipment at Green Bay, Wis., the consignee, Beneficial Home Products Co., repackaged a portion of the tablets into boxes labeled as described above and enclosed a copy of the above-mentioned leaflets in each box. The leaflets had been printed locally for the consignee.

LIBELED: 7–14–54, E. Dist. Wis.

CHARGE: 502 (a)—the labeling of the article while held for sale, namely, the box label and the leaflet enclosed in each box, contained false and misleading representations that the article was an adequate and effective treatment for all arthritic and rheumatic disorders, whether acute or chronic, and that continuous use could cure such diseases or conditions.

DISPOSITION: 8–27–54. Default—destruction.

4574. Rheumago tablets. (F. D. C. No. 37062. S. No. 56–269 L.)

QUANTITY: 3 10,000-tablet cartons, 1 5,000-tablet carton, and 27 packages, 3 84-tablet btls. each, at Cincinnati, Ohio, in possession of Hy-Pure Laboratories, Inc.

SHIPPED: On 1–11–54, 4 10,000-tablet cartons were shipped from St. Louis, Mo., to Cincinnati, Ohio.

LABEL IN PART: (Btl.) "Hy-Pure Rheumago Tablets For Relief of Symptoms Arthritis Rheumatism 84 Tablets (EC), each containing: Sodium Salicylate, USP * * * 5 gr. Para-aminobenzoic Acid, Sod * * * 5 gr."

ACCOMPANYING LABELING: Leaflet designated "Quick, Complete Relief From Pains Of Rheumatism Arthritis Lumbago Try Rheumago Tablets."

RESULTS OF INVESTIGATION: The article in the above-mentioned bottles had been repackaged by the consignee from the cartons in which shipped. The leaflets were printed locally for the consignee.

LIBELED: 8–24–54, S. Dist. Ohio.

CHARGE: 502 (a)—The labeling of the article while held for sale contained false and misleading representations that the article was a sensational new treatment for rheumatism, arthritis, and lumbago; that para-aminobenzoic acid was a new drug; and that the article was an adequate and effective treatment for rheumatism, arthritis, and lumbago.

DISPOSITION: 9–3–54. Consent—claimed by the Hy-Pure Laboratories, Inc., and relabeled.

4575. **Alfalfacon tablets.** (F. D. C. No. 37022. S. No. 81–860 L.)

QUANTITY: 94 100-tablet btls. at Norman, Okla., in possession of B. E. Massey Drug Store.

SHIPPED: 5–7–54, in bulk, from Costa Mesa, Calif.

LABEL IN PART: (Btl.) "BEM 100 Tablets Alfalfacon Genuine Concentrated Dehydrated Alfalfa Tablets Each Tablet Contains: 8 Grains of Pure Concentrated Dehydrated Alfalfa Recommended Dose: Two Tablets Three Times A Day Or As Directed By Your Physician. Biologically Assayed And Distributed By B. E. Massey Drug Store, 206 E. Main, Norman, Oklahoma."

ACCOMPANYING LABELING: Display placards designated "For Arthritis And Rheumatism Get Alfalfacon Tablets."

RESULTS OF INVESTIGATION: Upon receipt of the bulk shipment of the tablets, the consignee repackaged the tablets into bottles relabeled as described above. The above-mentioned placards were displayed in the consignee's store.

LIBELED: 7–27–54, W. Dist. Okla.

CHARGE: 502 (a)—the labeling of the article while held for sale contained false and misleading representations that the article was an effective treatment for arthritis and rheumatism.

DISPOSITION: 9–16–54. Default—destruction.

4576. **Soya lecithin.** (F. D. C. No. 36844. S. No. 80–822 L.)

QUANTITY: 1 drum containing 15 pounds, and 11 ½-pound jars at Philadelphia, Pa., in possession of Thomas Martindale Co.

SHIPPED: 5–4–54, from Chicago, Ill.

ACCOMPANYING LABELING: Bulletins designated "Martindale Bulletin #6 * * * Lecithin * * * And Headaches, Sleeplessness And Nervousness."

RESULTS OF INVESTIGATION: The portion of the product in the jars was contained in the above-mentioned drum when shipped in interstate commerce, and, upon receipt by the consignee, was repacked into the jars. The bulletins were formulated and mimeographed by the consignee.

LIBELED: 6–23–54, E. Dist. Pa.

CHARGE: 502 (a)—the accompanying labeling of the article while held for sale contained false and misleading representations that article was effective in the treatment of headaches, sleeplessness, nervousness, tiredness, high blood pressure, diabetes, arthritis, and low blood pressure, and that lecithin is a dietary essential frequently deficient in human diets.

DISPOSITION: 9–28–54. Default—destruction.

4577. Alfalfa meal, alfalfa seed, and powdered mixture of alfalfa meal and seed. (F. D. C. No. 36193. S. Nos. 38–979/82 L, 38–984/5 L.)

QUANTITY: 300 100-lb. bags of *alfalfa meal*, 1 100-lb. drum of *alfalfa seed*, and 19 100-lb. drums, 6 cases, 12 8-oz. btls. each, 33 cases, 12 200-capsule btls. each, and 11 cases, 12 300-tablet btls. each, of a *powdered mixture of alfalfa meal and seed* at Pulaski, Va., in possession of Lucerne Corp.

SHIPPED: (Alfalfa meal) 10–9–52, from Vernalis, Calif., and (alfalfa seed) 3–17–53, from Crows Landing, Calif.

LABEL IN PART: (Btl.) "Pulvacerne."

ACCOMPANYING LABELING: Pamphlets entitled "The Pulvacerne Story."

RESULTS OF INVESTIGATION: The Lucerne Corp. caused portions of *alfalfa meal* and *alfalfa seed*, which had been shipped to it in bulk drums, to be mixed, powdered, capsuled, tableted, and labeled, and caused also the above-mentioned pamphlets to be associated with the article in the drums and in the bottles.

LIBELED: On or about 12–22–53, W. Dist. Va.

CHARGE: 502 (a)—the labeling of the articles while held for sale contained false and misleading representations that the articles constituted an adequate and effective treatment for the pain and swelling of arthritis and rheumatism.

DISPOSITION: 3–23–54. Consent—claimed by Lucerne Corp. The *alfalfa meal* was sold for use in the manufacture of animal feed and the *alfalfa seed* was sold for planting purposes. The *powdered mixture of alfalfa meal and seed* was destroyed, except for 1 case of 12 200-capsule btls. which was used for clinical testing.

4578. Dried whole leaves. (F. D. C. No. 37018. S. No. 74–044 L.)

QUANTITY: 600 ½-lb. bags at Santa Monica, Calif., in possession of Windsor Llewellyn, d/b/a Maya-Leaf Importers.

SHIPPED: 2–9–54, from Poaz, Costa Rica.

ACCOMPANYING LABELING: Pamphlets designated "Maya-Leaf An infusion for relief from Rheumatoid Arthritis."

RESULTS OF INVESTIGATION: The above-mentioned pamphlets were printed for the consignee and were brought by him into association with the product. It was assumed that the product consisted of dried leaves from the plant Cassia reticulata, Willd.

LIBELED: 7–26–54, S. Dist. Calif.

CHARGE: 502 (a)—the accompanying labeling of the article while held for sale contained false and misleading representations that the article was an effective treatment for arthritis, rheumatism, stomach infections, colds, dysentery, and high blood pressure.

DISPOSITION: 8–16–54. Default—destruction.

4579. Uranium ore. (F. D. C. No. 37057. S. No. 85–865 L.)

QUANTITY: 5 tons at Canistota, S. Dak., in possession of Joel J. Strom, t/a Canistota Uranium Health Center.

SHIPPED: During May 1954, from Butte, Mont.

ACCOMPANYING LABELING: Booklet entitled "Health Is Your Most Prized Treasure," a flyer designated "Merry Widow Mine," and leaflets designated "Radioactivity Does Wonders . . . Health Is Your Most Prized Treasure."

RESULTS OF INVESTIGATION: The *uranium ore* was stored after shipment in the walls and under the floor of a one-room cabin known as the Canistota Uranium Health Center. The room was provided with benches upon which the patient would sit for a period of 1 hr. while undergoing the "treatment" provided by the purported radioactivity of the ore. The accompanying labeling of the ore was displayed on the premises of the Canistota Uranium Health Center, and was distributed by the consignee to prospective patients.

LIBELED: 8–24–54, Dist. S. Dak.

CHARGE: 502 (a)—the accompanying labeling of the article while held for sale contained false and misleading representations that the article provided an adequate and effective treatment for arthritis, rheumatism, asthma, sinus trouble, and skin disorders.

DISPOSITION: Joel J. Strom, claimant, filed an answer on or about 9–14–54, denying that the article was misbranded as alleged in the libel. Thereafter, the Government served interrogatories upon the claimant, which were answered by him showing, among other things, that the article was transported from Montana in a truck owned by the claimant. A motion to amend the libel was then filed by the Government to add the charges that when the article was introduced into interestate commerce it was misbranded (1) under 502(a) in that its accompanying labeling, namely, the above-mentioned booklet and flyer, contained false and misleading representations as described above and (2), in the alternative, under 502(f)(1) in that its labeling failed to bear adequate directions for use in the treatment of the diseases and conditions for which the article was intended.

On 12–15–54, an order to amend the libel as proposed in the Government's motion was entered, and, pursuant to motion by the claimant an order was entered for the withdrawal of the claimant's claim and answer. Thereafter, on the same day, a decree of condemnation and destruction was entered against the article.

4580. Triethylene glycol and vaporizer device. (F. D. C. No. 36835. S. Nos. 78–696/7 L.)

QUANTITY: An unknown number of 4-oz. btls. of *triethylene glycol* and an unknown number of cartons containing 1 *Insect-O-Lite vaporizer*, 1 1-oz. bag of *Insectane*, and 1 4-oz. btl. of *triethylene glycol*, at Cincinnati, Ohio.

SHIPPED: *Triethylene glycol* was shipped in bulk from South Charleston, W. Va., on 3–6–54, 4–22–54, and 4–24–54.

LABEL IN PART: (Btl.) "Tricol * * * Triethylene Glycol * * * for use in Insect-O-Lite Vaporizer for disinfection of the air, destruction of air-borne bacteria and virus germs * * * Insect-O-Lite Co., Inc. Cincinnati 6, Ohio"; (carton) "One Insect-O-Lite Vaporizer with Insectane * * * Tricol."

ACCOMPANYING LABELING: Placards designated "Insect-O-Lite—Vapor Lamp"; window streamers designated "Destroy Insects with Insect-O-Lite"; circulars designated "Kills Crawling and Flying Insects," "Let 'em Have Both Barrels," "Insect-O-Lite Vapor Lamp," and "Insect-O-Lite Vaporizer with Tricol"; and shipping case labels designated "One Insect-O-Lite Vaporizer with Insectane * * * Tricol."

RESULTS OF INVESTIGATION: The *triethylene glycol* in bulk was received by Bernard's Laboratories at Cincinnati, Ohio, from South Charleston, W. Va., and was repackaged by that firm on the order of Insect-O-Lite Co., Inc., Cincinnati, Ohio, into bottles labeled as described above. A number of the bottles were then delivered by the Insect-O-Lite Co., Inc., to the Norvelle Co., which placed each bottle into a carton labeled as described above, together with 1 *Insect-O-Lite vaporizer*, 1 1-oz. bag of *Insectane*, and a copy of a circular designated "Insect-O-Lite Vaporizer with Tricol." The Norvelle Co. then delivered a number of assembled Insect-O-Lite cartons to the Insect-O-Lite Co., Inc., for distribution by that firm.

LIBELED: 6–14–54, S. Dist. Ohio.

CHARGE: 502(a)—the labeling of the *triethylene glycol* and the *Insect-O-Lite vaporizer* while held for sale contained false and misleading representations that the articles were effective for preventing colds, streptococci infection, influenza, pneumonia, measles, mumps, scarlet fever, rheumatic fever, catarrhal fever, tonsillitis, otitis media, chickenpox, sinusitis, infections due to *Bacillus coli* and *Bacillus subtilis*, throat infections, and respiratory infections.

DISPOSITION: 6–22–54. Consent—claimed by Insect-O-Lite Co., Inc., and relabeled.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4561 TO 4580

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4579) Seizure contested.

U. S. GOVERNMENT PRINTING OFFICE: 1956

D. D. N. J., F. D. C. 4581–4600 Issued March 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4581–4600

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation; (2) criminal proceedings which were terminated upon pleas and verdicts of guilty and upon motion for acquittal; (3) injunction proceedings terminated with the entry of injunctions; and (4) contempt proceedings for violation of an injunction which were terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal, injunction, and contempt proceedings are against the *firms or individuals* charged to be responsible for violations.

Similar actions with respect to products alleged to be in violation while held for sale after shipment in interstate commerce are reported in other supplements.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 9, 1956.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see No. 4583; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4583.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4581–4600

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling; and, Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of penicillin or aureomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4581. Vaginal suppositories. (Inj. No. 279.)

COMPLAINT FOR INJUNCTION FILED: 5–20–54, N. Dist. Ill., against Harriet McGill Fickinger, t/a Dr. J. A. McGill Co., Not Inc., and Clara H. Nielsen, general manager of the business, to enjoin the interstate shipment of the above-mentioned article.

LABEL IN PART: (BOX) "Contents 6 Suppositories Orange Blossom Suppositories Active Ingredients of Each Suppository: Alum—Borax—Petrolatum Prepared by DR. J. A. McGILL CO., Not Inc. 2001–3 Indiana Ave., Chicago 16, Ill. For Simple Irritations Of The Vaginal Tract Directions—Remove tinfoil and at bed time insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days. The use of Orange Blossom Suppositories is not recommended at the menstrual period or during pregnancy."

ACCOMPANYING LABELING: Leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

CHARGE: The complaint alleged that the article, when used as a suppository in the vagina in the manner recommended in its labeling, or in any other dosage, was unsafe and dangerous to health and that the article, because of its alum content, may cause serious injury by destroying normal, healthy tissue in the vaginal tract and that the defendants had been and still were engaged in preparing, selling, and introducing into interstate commerce such article which was misbranded under 502 (a), and that its labeling, when con-

sidered in its entirety and in the setting in which it was used, created the false and misleading impression that the article was a safe, adequate, and effective treatment for simple irritations of the vaginal tract; and under 502 (j), in that the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling.

The complaint further alleged that if the defendants were forced by an injunction to refrain from using the existing labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article in interstate commerce without labeling stating the dosage for the article and without labeling stating the conditions and purposes for which the article was intended; and that, in such case, the article would be misbranded under 502 (f) (1), in that its labeling would fail to bear adequate directions for use because of the omission from its labeling of the dosage for the article and because of the omission from its labeling of statements of the conditions and purposes for which the article was intended.

DISPOSITION: 12–23–54. The defendants having consented, the court entered a decree of injunction perpetually enjoining the defendants from introducing into interstate commerce the article, or any other article of similar composition, which was misbranded under 502 (a), 502 (f) (1), and 502 (j).

4582. **Vaginal suppositories (11 seizure actions).** (F. D. C. Nos. 36839, 36840, 37064, 37083, 37084, 37092, 37119, 37274, 37368, 37563, 37611. S. Nos. 43–171 L, 43–173 L, 47–896 L, 67–955 L, 74–102/3 L, 79–885 L, 79–888 L, 80–067 L, 81–080 L, 86–437 L, 6–261/2 M, 14–247 M.)

QUANTITY: 11,048 boxes at Los Angeles, Oakland, Sacramento, and San Francisco, Calif., New Orleans, La., Indianapolis, Ind., Houston, Tex., St. Louis, Mo., and Cleveland, Ohio.

SHIPPED: Between 3–19–54 and 12–13–54, from Chicago, Ill., by Dr. J. A. McGill Co.

LABEL IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum—Borax—Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

ACCOMPANYING LABELING: Leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

LIBELED: Between 6–16–54 and 1–17–55, N. Dist. Calif., S. Dist. Calif., E. Dist. La., S. Dist. Ind., S. Dist. Tex, E. Dist. Mo., N. Dist. Ohio.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment of diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and, 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions—Remove tinfoil and at bed time insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: Between 6–29–54 and 3–3–55. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4583. P. B. S. C. drug and Anti-Bacterial Root Canal Cement. (F. D. C. No. 33776. S. Nos. 91–830 K, 23–140 L, 23–485 L.)

INFORMATION FILED: 7–9–53, S. Dist. N. Y., against Sultan's Pharmacy, Inc., New York, N. Y., and John O. Cramer, president.

SHIPPED: *P. B. S. C. drug* on 11–20–50 and *Anti-Bacterial Root Canal Cement* on 1–7–52 and 2–12–52, from New York to New Jersey.

LABEL IN PART: (Box) "P. B. S. C." and "Cohen-Luks Anti-Bacterial Root Canal Cement Contains: Aureomycin, Silver, Rosin ZnO, with a Balsamic-Eucalyptus Comp."

CHARGE: *P. B. S. C. drug.* 502 (e) (2)—when shipped its label bore no statement of the active ingredients; and, 502 (l)—it was a drug composed in part of penicillin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to the law.

Anti-Bacterial Root Canal Cement (1–7–52 shipment). 501 (c)—its strength differed from that which it was represented to possess since it did not contain aureomycin as represented; and, 502 (a)—the label statement "Contains aureomycin" was false and misleading.

Anti-Bacterial Root Canal Cement (2–12–52 shipment). 502 (l)—it was represented as a drug composed partly of aureomycin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to the law.

P. B. S. C. drug and both shipments of *Anti-Bacterial Root Canal Cement.* 502 (b) (2)—the labels of the drugs bore no statement of the quantity of contents.

PLEA: Guilty by corporation to all 4 counts of information and by Cramer to 3 counts relating to *Anti-Bacterial Root Canal Cement.*

DISPOSITION: 2–10–55. Corporation fined $400; Cramer given sentence of 6 months in jail, which was suspended, and placed on probation for 6 months.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4584. Lipitrons capsules and Super Lipitrons capsules. (F. D. C. No. 33791. S. Nos. 14–755 L, 15–706 L, 30–995 L.)

INFORMATION FILED: 8–6–53, Dist. Nebr., against Vitamin Industries, Inc., Omaha, Nebr., and Joseph L. Zweiback, president.

SHIPPED: Between 8–3–51 and 1–11–52, from Omaha, Nebr., to Peoria, Ill., and Topeka, Kans.

CHARGE: The articles were charged to be misbranded under 502 (a) and 502 (f) (1). The nature of such charges is set forth in the court's opinion quoted below.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 2–22–54, and on 3–31–55, the court handed down the following memorandum opinion and decision in which the defendants were found guilty and fined:

*See also No. 4581.

DELEHANT, *District Judge:* "By information in three counts, the plaintiff charges the defendants with the violation of Title 21 U. S. C. A., Sections 331 and 333. The nature of the charge under Count I may be gathered from a copy of that count which is set out in a footnote.[1] Count II differs from Count

[1] "The United States Attorney charges :
"That Vitamin Industries, Inc., a corporation organized and existing under the laws of the State of Nebraska and trading and doing business at 1511 Davenport Street, Omaha, State of Nebraska, and Joseph L. Zweiback, an individual, at the time hereinafter mentioned president of said corporation, the defendants herein, did, within the Omaha Division of the District of Nebraska, within the period from on or about August 3, 1951, to on or about August 6, 1951, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Omaha, State of Nebraska, for delivery to Topeka, State of Kansas, consigned to the Jayhawk Drug Co., a number of bottles containing a drug ;
"That displayed upon said bottles was certain labeling which consisted, among other things, of the following printed and graphic matter :

Guardian 100 Caplets Lipitrons
High Potency Lipotropic Formula
Each Caplet Contains :

Vitamin B_1	15 mgm.
Vitamin B_2	6 mgm.
Vitamin C	50 mgm.
Niacinamide	30 mgm.
Calcium Pantothenate	3 mgm.
Vitamin B_6	0.5 mgm.
Desiccated Whole Liver	175 mgm.
Dried Debittered Yeast	175 mgm.
Choline Dihydrogen Citrate	20 mgm.
Inositol	20 mgm.
dl-Methionine	20 mgm.
Iron as Ferrous Gluconate	30 mgm.
Folic Acid	0.1 mgm.
Vitamin B_{12} (oral conc.)	3 mgm.

"That accompanying said drug was certain additional labeling relating to said drug, namely, a poster entitled 'If you are over 35 If You Are Getting That Growing Old Feeling * * * A True Geriatric Formula Designed Especially For Advanced Age Groups To Help You Enjoy Life Again * * *';
"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was misbranded within the meaning of 21 U. S. C. 352 (a) 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm., which appeared on the bottle label, was false and misleading in that said statement represented and suggested that said drug possessed significant lipotropic properties; whereas, said drug did not possess significant lipotropic properties ;
"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the statement 'Each Caplet Contains * * * Choline Dihydrogen Citrate 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm.,' which appeared on the bottle label, was misleading in that said statement represented, suggested, and created the impression that said drug, when used as directed, would provide significant amounts of Choline dihydrogen citrate, inositol, and dl-methionine; whereas, said drug, when used as directed, would not provide significant amounts of choline dihydrogen citrate, inositol, and dl-methionine ;
"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the aforesaid additional labeling of said drug contained the following statements, to wit :

If you are over 35 If You Are Getting That Growing Old Feeling A True Geriatric Formula Designed Especially For Advanced Age Groups To Help You Enjoy Life Again * * *

which statements were false and misleading in that said statements when read in the light of the newspaper advertisements for said drug which appeared in the Topeka State Journal for August 6, 1951, and in the Topeka Daily Capital newspaper for August 7, 1951, represented, suggested, and created the impression that said drug was effective in the treatment of persons more than 35 years old suffering from a growing old feeling, tiredness, weakness, and run-down condition, and that it was effective to help recapture lost vitality and strength ; to combat nervousness and lack of vigor and energy ; to help one to really begin to enjoy life again ; and to attack true basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, and other symptomatic conditions of deficiencies in nutritional intake ; whereas, said drug was not effective in the treatment of persons more than 35 years old suffering from a growing old feeling, tiredness, weakness, and run-down condition ; and was not effective to help recapture lost vitality and strength ; to combat nervousness and lack of vigor and energy ; to help one to really begin to enjoy life again ; or to attack true basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, or other symptomatic conditions of deficiencies in nutritional intake ;
"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (f) (1) in that the labeling of said drug failed to bear adequate directions for use for the purposes and conditions for which it was intended, namely, for the treatment of persons over 35 years old suffering from a growing old feeling, tiredness, weakness, and run-down condition ; to help recapture lost vitality and strength ; to combat nervousness

I only in these respects: (a) It charges shipment between September 20, 1951, and October 4, 1951; (b) It alleges that the labeling displayed upon the bottles also 'accompanied' the bottles; (c) It alleges that the statement quoted in the fifth paragraph of footnote 1, supra, was both false and misleading; and (d) It alleges newspaper advertising in the September 24, 1951, issue of Topeka State Journal and the September 25, 1951, issue of Topeka Daily Capital. Count III, though similar to Count I, differs in this, that it alleges: a) a single shipment on or about January 11, 1952, to Peoria, Illinois, consigned to Peoria Health Food Center, of a number of bottles, containing a drug, b) upon which bottles was labeling consisting, among other things, of the following language:

Guardian 100 Capsules
Super Lipitrons
Vitamin B_{12} High Potency
B Complex with Iron & Vitamin C
Each Capsule Contains:

Vitamin B_1	15 mgm.
Vitamin B_2	6 mgm.
Vitamin C	50 mgm.
Niacinamide	30 mgm.
Calcium Pantothenate	3 mgm.
Liver Concentrate	30 mgm.
Vitamin B_6	0.5 mgm.
Choline Dihydrogen Citrate	20 mgm.
Inositol	20 mgm.
dl-Methionine	20 mgm.
Iron as Ferrous Gluconate	30 mgm.
Folic Acid USP	0.1 mgm.
Vitamin B_{12} (Crystalline)	3 mcg.

and, c) newspaper advertising in the January 22, 1952, issue of Peoria Journal, and d) falsity and misbranding of the drug specified in respects and particulars as set out in a footnote.[2]

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and lack of vigor and energy; to help one to really begin to enjoy life again, and to attack true basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, and other symptomatic conditions of deficiencies in nutritional intake, which are the purposes and conditions for which said drug was offered in the newspaper advertisements appearing in the August 6, 1951, issue of the Topeka State Journal and the August 7, 1951, issue of the Topeka Daily Capital newspaper, which newspaper advertisements were sponsored by and on behalf of said defendants.

"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the statement 'Each Capsule Contains * * * Choline Dihydrogen Citrate 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm.' which appeared on the bottle label, was misleading in that said statement represented, suggested, and created the impression that said drug, when used as directed, would provide significant amounts of choline dihydrogen citrate, inositol, and dl-methionine, whereas, said drug, when used as directed, would not provide significant amounts of choline, dihydrogen citrate, inositol, and dl-methionine."

[2] "That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the aforesaid additional labeling of said drug contained the following statements, to wit:

If You Are Over 35 If You Are Getting That "Growing Old" Feeling * * * A True Geriatric Formula Designed Especially For Advanced Age Groups To Help You Enjoy Life Again * * *

which statements were false and misleading in that said statements, when read in the light of the newspaper advertisements for said drug, which appeared in the Peoria Journal for January 22, 1952, represented, suggested and created the impression that said drug was effective in the treatment of persons over 35 years old to combat that feeling of growing old; to relieve those suffering from tiredness, weakness, nervousness, and run-down condition; to overcome the deficiencies that help drag one down; for premature advancing age; to furnish a whole new world of buoyant energy, vitality and strength by relieving and overcoming the basic causes of their nutritional deficiencies; to help those who feel years older than their age to enjoy life again; to regain vigor and vibrant energy; and to enable thousands of men and women to work harder, and to cause the difference between their old listless dragged-out feeling and new vitality; whereas, said drug was not effective in the treatment of persons over 35 years old to combat that growing old feeling; to relieve those suffering from tiredness, weakness, nervousness, and run-down condition; to overcome the deficiencies that help drag one down; for premature advancing age; to furnish a whole new world of buoyant energy, vitality and strength by relieving and overcoming the basic causes of their nutritional deficiencies; to help those who feel years older than their age to enjoy life again; to regain vigor and

"Each defendant pleaded not guilty as to each count of the information. Trial by jury was waived and the case was tried before the court without a jury. Much of the evidence was received under a stipulation. That is especially true in respect of the business relationship of the defendants, the making of the alleged shipments, the contents of the labels upon the bottles and the shipment of some advertising material in the way of posters, and the publication of newspaper advertising. Both the government and the defendants supplemented the stipulation with oral testimony and also with exhibits beyond those introduced in association with the stipulation.

"The facts are now found by the court. They may be considered to have been stipulated except to the extent that they are declared to be the court's findings upon unstipulated evidence.

"Of the defendants, Vitamin Industries, Inc., at all material times was, and still is, a corporation duly organized and existing under the laws of Nebraska, with its principal place of business in Omaha, Nebraska, and Joseph L. Zweiback at all such times was and is its principal stockholder and accountable manager.

"Shortly prior to August 10, 1951, the defendants within the Omaha Division of this District introduced and caused to be introduced for shipment in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company at Topeka, Kansas, a number of bottles, each containing a drug bearing the label of, and in part identifying the contents as, 'Guardian Lipitrons.' Affixed to and displayed upon each of said bottles was a label containing the following printed and graphic material:

Guardian 100 Caplets Lipitrons High Potency Lipotropic Formula Each Caplet Contains:

Vitamin B_1	15 mgm.
Vitamin B_2	6 mgm.
Vitamin C	50 mgm.
Niacinamide	30 mgm.
Calcium Pantothenate	3 mgm.
Vitamin B_6	0.5 mgm.
Desiccated Whole Liver	175 mgm.
Dried Debittered Yeast	175 mgm.
Choline Dihydrogen Citrate	20 mgm.
Inositol	20 mgm.
dl-Methionine	20 mgm.
Iron as Ferrous Gluconate	30 mgm.
Folic Acid	0.1 mgm.
Vitamin B_{12} (Oral conc.)	3 mgm.

The same label also contained the following language:

A DIETARY SUPPLEMENT

DIRECTIONS: Adults—One capsule per day or as directed by the physician. Each Capsule supplies the following ration of the minimum adult daily requirements: 1500% of Vitamin B_1, 300% of Vitamin B_2, 167% of Vitamin C, and 33% of Iron. The daily adult requirement for Niacina-

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vibrant energy; and to enable thousands of men and women to work harder, and to cause the difference between their old, listless dragged-out feeling and new vitality.

"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (f) (1) in that the labeling of said drug failed to bear adequate directions for use for the purposes and conditions for which it was intended, namely, for the treatment of persons over 35 years old to combat that feeling of growing old; to relieve those suffering from tiredness, weakness, nervousness and run-down condition; to overcome the deficiencies that help drag one down; for premature advancing age; to furnish a whole new world of buoyant energy, vitality and strength by relieving and overcoming the basic causes of their nutritional deficiencies: to help those who feel years older than their age to enjoy life again; to regain vigor and vibrant energy; and to enable thousands of men and women to work harder, and to cause the difference between their listless dragged-out feeling and new vitality; which are the purposes and conditions for which said drug was offered in the newspaper advertisements appearing in the January 22, 1952, issue of the Peoria Journal, which newspaper advertisements were sponsored by and on behalf of said defendants."

mide and Vitamin B_6 has not been established. The need in Human Nutrition for Calcium Pantothenate, Choline, Inositol, dl-Methionine, Folic Acid and Vitamin B_{12} has not been established.

"At approximately the same time and in connection with the shipment of the same drug, the defendants also shipped in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company, 1001 Kansas Avenue, Topeka, Kansas, a number of display posters entitled, and bearing the introductory language,

If you are over 35
If you are getting that growing old feeling . . .
A True Geriatric Formula Designed
Especially for Advanced Age Groups To Help
You Enjoy Life Again . . . .

Those posters were by the defendants designed to be used for the purpose of interesting prospective customers in the purchase, and stimulating the sale, of the drug thus transported. On August 10, 1951, some of such posters, the exact number being uncertain, were publicly displayed in the Jayhawk Drug Store, 1001 Kansas Avenue, Topeka, Kansas, in such manner that each such poster could be and was used in the disposition and sale of the drug.

"On August 6 and 7, 1951, a full page newspaper advertisement for the drug, 'Lipitrons' appeared in Topeka State Journal and Topeka Daily Capital, respectively, newspapers of general circulation in and around Topeka, Kansas, which advertisements, and each of them, were sponsored and paid for in whole or in part by the defendants. Each such advertisement, in large and attention challenging type, opened with the words,

If you are over 35 years old If you are getting that "growing old" feeling Science has now found how to fight that feeling of "growing old"

LIPITRONS

For You if you feel tired and weak and Rundown!
For You to help you Recapture Lost Vitality and Strength!
For You to combat Nervousness, Lack of Vigor and Energy!

Much other material in that advertising advanced the contention that the drug, 'Lipitrons' was effective to remedy the so-called feeling of 'growing old' and to intercept the experience of feeling tired, weak and rundown, and to help its takers to recapture lost vitality and strength and to combat nervousness, and lack of vigor and of energy and to enjoy life again. And again, in attractive large letters each advertisement closed with the following advice: 'Start yourself, right now, taking a single Lipitron each day! Mail and phone orders filled same day received. JAYHAWK DRUG.'

"Shortly prior to October 16, 1951, and in any event within three years prior to the date of the filing of the information herein, the defendants within the Omaha Division of this District introduced and caused to be introduced for shipment in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company at Topeka, Kansas, a number of bottles, each containing a drug bearing the label of, and in part identifying the contents as, 'Guardian Lipitrons.' Affixed to and displayed upon each of said bottles was a label containing the same description of contents and directions already quoted in connection with the previous similar shipment. At approximately the same time, and in connection with the shipment last above mentioned, the defendants also shipped in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company, 1001 Kansas Avenue, Topeka, Kansas, a number of display posters entitled and bearing the introductory language quoted, supra, from similar posters already identified. These latter posters were by the defendants designed to be used for the purpose of interesting prospective customers in the purchase, and stimulating the sale, of the drug thus transported. On October 16, 1951, some of such posters, the exact number being uncertain, were

publicly displayed, along with some of the bottles containing the drug, in the Jayhawk Drug Store, 1001 Kansas Avenue, Topeka, Kansas, in such manner that each such poster could be and was used in the disposition and sale of the drug.

"On September 24 and 25, 1951, newspaper advertisements, each an entire page in length and approximately two-thirds page in width, devoted largely, but not entirely, to the advertisement of the drug, 'Lipitrons,' appeared in Topeka State Journal and Topeka Daily Capital, respectively. Both of those advertisements were sponsored by and paid for, in whole or in part, by the defendants. Those advertisements contained all of the material quoted above from the advertisements of August 6 and 7, as well as much other material advancing the contention that the drug, 'Lipitrons' was effective to remedy the so-called 'feeling of growing old and to intercept the experience of feeling tired, weak and rundown, and to help its takers to recapture lost vitality and strength and to combat nervousness and lack of vigor and of energy, and to enjoy life again.' The advertisements of September 24 and 25, 1951, closed with the designation of 'Jayhawk Drug, 1001 Kansas Avenue' which it described as featuring 'every vitamin for every purpose' and as 'largest exclusive vitamin institution in Topeka.'

"On or about January 11, 1952, the defendants shipped in interstate commerce from Omaha, Nebraska, to Peoria, Illinois, consigned to Peoria Health Food Center, 131 North Jefferson Avenue, Peoria, Illinois, a number of bottles, each bearing a label designating its contents as 'Guardian Super Lipitrons.' Affixed to and displayed upon each of said bottles was a label containing the following printed and graphic material:

EACH CAPSULE CONTAINS:

Vitamin B_1	15 mgm.
Vitamin B_2	6 mgm.
Vitamin C	50 mgm.
Niacinamide	30 mgm.
Calcium Panthotenate	3 mgm.
Vitamin B_6	0.5 mgm.
Liver Concentrate	30 mgm.
Choline Dihydrogen Citrate	20 mgm.
dl-Methionine	20 mgm.
Inositol	20 mgm.
Iron as Ferrous Gluconate	30 mgm.
Folic Acid	0.1 mgm.
Vitamin B_{12} USP (Crystalline)	3 mcg.

And the same label also contained the following printed and graphic material:

A DIETARY SUPPLEMENT

DIRECTIONS: Adults—One capsule per day or as directed by the physician. Each capsule supplies the following ration of the minimum adult daily requirements: 1500% of Vitamin B_1, 300% of Vitamin B_2, 167% of Vitamin C, and 33% of Iron. The daily adult requirement for Niacinamide and Vitamin B_6 has not been established. The need in Human Nutrition for Calcium Pantothenate, Choline, Inositol, dl-Methionine, Folic Acid and Vitamin B_{12} has not been established.

"At or about the same time the defendants also shipped from Omaha, Nebraska, to Peoria, Illinois, and to the said Peoria Health Food Center, as consignee, a number of display posters entitled, and bearing the introductory language:

IF YOU ARE OVER 35
If You Are Getting That
"GROWING OLD" feeling
Advanced Formula
LIPITRONS, A True Geriatric

Formula Designed Especially For
Advanced Age Groups
To Help You
ENJOY LIFE AGAIN

Those posters were by the defendants designed to be used for the purpose of interesting prospective customers in the purchase, and stimulating the sale, of the drug described as 'Guardian Super Lipitrons' thus transported, and along with bottles containing such 'Guardian Super Lipitrons' were publicly displayed by the said Peoria Health Food Center.

"On January 22, 1952, a newspaper advertisement, approximately three-fourths of a page long and five columns wide, appeared in the Peoria Journal, a newspaper of general circulation in and around Peoria, Illinois, which advertisement was sponsored and paid for, in whole or in part, by the defendants. Such advertisement in large and attention challenging type opened with the words:

IF YOU ARE OVER 35 YEARS OLD!
IF YOU FEEL "OLD" BEFORE YOUR TIME!
NOW! Combat that Feeling of "Growing Old"!

Much other material in that advertisement advanced the contention that the drug 'Lipitron' was effective to remedy the so-called feeling of 'growing old' and to intercept the experience of feeling tired, weak and rundown and to help its takers to recapture lost vitality and strength, and to combat nervousness and lack of vigor and energy, and to enjoy life again. The advertisement closed with the identification of 'HEALTH FOOD CENTER, 131 Jefferson Ave., Peoria' as the advertiser.

"The composition of the drugs contained in the several bottles above referred to was exactly the same as to nutrition and quality, with respect to each exhibit, as stated and represented on the printed label on each such exhibit.

"While the several posters above mentioned were prepared by the defendants and by them were designed for use in the promotion and furtherance of the sale of the drugs shipped by the defendants to the several indicated consignees, the posters were not in any instance transported in the same package, carton or wrapper as a shipment of the drugs to which they respectively referred. The posters were, however, shipped at about the same times when the related shipments of drugs were made to the several consignees of the posters.

"Concerning the several newspaper advertisements, it is not proved—nor, indeed, is it charged—that the newspaper mats or plates, or other material for their printing or composition, were, by the defendants, or either of them, shipped at any time in interstate commerce. The defendants are shown merely to have sponsored and, wholly or in part, to have paid for those advertisements which were timed strategically to inspire and stimulate the local retail sales of the drugs which were by the defendants introduced into and transported by interstate commerce.

"Not by stipulation, but upon the oral evidence[3] received on the trial, the following further findings are made:

"As a practical matter it is impossible, without immediate and individual clinical examination of a person, to prescribe for his treatment the taking of the so-called vitamin drugs. His need for specific vitamin bearing substances and for appropriate quantities thereof must first be established. And this can not be done by the manufacturer of drugs upon a generalized basis applicable alike to all potential patients through resort to self diagnosis. Attempts in that direction are either without any effect or actually evil through

[3] It can hardly be considered that the oral evidence is in dispute. For the plaintiff three scientific expert witnesses testified. One was the president of the American Geriontial Society, a physiologist of world-wide celebrity, with many years of experience in teaching and research, of which more than fifty years were spent in the University of Chicago. The second was a Doctor of Philosophy and a Doctor of Medicine, the professor of Biological Chemistry and Nutrition in the College of Medicine of Creighton University, a man of preeminence and distinction in his field. And the third was a practicing physician of Omaha who is also an instructor in internal medicine and geriatrics in the College of Medicine of the University of Nebraska. Their testimony was not repelled by opposing evidence. Each of them was subjected to appropriate cross examination. But the cross examination was ineffective to impair their direct evidence.

the reception of improper substances or of generally meritorious substances in doses unsuitable to the needs of the patients.

"Assuming the presence, in the transported capsules of the drugs, of the elements in the quantities designated on the several bottle labels, the capsules if taken in the quantities suggested on the labels could have no possible retarding or corrective effect upon the aging process or upon the 'feeling of growing old.' Nor would they have any effect in enabling their takers to 'recapture lost vitality' if the loss of vitality were incident to old age. There is actually no available medicinal remedy for the loss of vitality in consequence of old age

"While certain of the ingredients of the tablets, e. g., Choline Dihydrogen Citrate, Inositol, and dl-Methionine, are recognized as lipitrophic agencies, and are helpful in some cases, the tablets here involved contain such small quantities of those ingredients that their lipitrophic effect in any instance would be slight, and, in cases of substantial deficiency, altogether insignificant.

"Despite the representations of the labels, the product involved is not actually a 'high potency lipitron' or a 'super lipitron' and may not accurately or properly be so characterized.

"The charge against the defendants does not involve any impurity or adulteration, and the evidence discloses no such action. The products shipped, in respect of the general nature, quantity and purity of their ingredients were as represented. They are not dangerous or harmful to human health.[4]

"The labeling of the transported products did not bear adequate directions for use for the several purposes and conditions for which it was intended, as such purposes and conditions were enumerated and set out in the several newspaper advertisements whose publication has already been found.

"On September 5, 1952, in the court of this division and district, United States of America filed in Civil Action No. 79–52 a libel of information praying for the forfeiture of a large quantity of drugs, including sundry items designated as Super Lipitrons in the possession of the corporate defendant to this action, upon the ground that such drugs were misbranded while held for sale after shipment in interstate commerce within the meaning of Title 21 U. S. C. A., Section 352 (f) (1) in that the label thereon failed to bear adequate directions for the use for which the drugs was intended. On the same day an order for writ of attachment, monition and publication was made and given by this court in such civil action, directing that, besides the publication of an appropriate citation, a copy of such citation be served on the president of the corporate defendant hereto. Thereafter, on September 17, 1952, the corporate defendant hereto made answer to such libel of information, claiming to be the owner of said drugs, consenting to the entry of a decree of condemnation or forfeiture thereof as misbranded and praying for the redelivery to it of such drugs, pursuant to the terms and provisions of Title 21 U. S. C. A., Section 334 (d). On September 17, 1952, with the written approval of counsel for United States of America and counsel for the corporate defendant hereto, decree of condemnation was entered in said civil proceeding in which, among other things, it was directed that the marshal for this district release said drugs to the custody of the corporate defendant hereto under appropriate bond, to the end that the corporate defendant hereto might within a time limited in said decree bring said drug into compliance with the provisions of the Federal Food, Drug and Cosmetic Act under the supervision of a duly authorized representative of the Federal Security Administrator by destroying any portion of such drugs which might be misbranded and by properly relabeling the remainder of said drugs and otherwise conforming with the requirements of the duly authorized representative of the Administrator. Thereafter, the corporate defendant hereto, under the direction and to the satisfaction of the Federal Security Administrator, relabeled the drugs seized in said civil action which were, thereupon, by the Administrator released to the corporate defendant hereto for disposition, and on March 31, 1953, upon application by the United States of America, an order of this court was duly made and given exonerating the bond and discharging

[4] This finding must not be understood to impair the finding of the inadequacy of the products to cure, correct or improve the conditions for which they are recommended by the defendants. The court recognizes that a measure of danger or harm may result from hope thus inspired and left unsatisfied.

the surety in connection with the bond theretofore given by the corporate defendant in such civil proceeding.

"By Title 21 U. S. C. A., Section 331, it is provided that:

> The following acts and the causing thereof are hereby prohibited:
> (a) The introduction or delivery for introduction into interstate commerce of any . . . . . drug . . . . . that is . . . . . misbranded.

"Penalties for the violation of Title 21 U. S. C. A., Section 331 are provided by Title 21 U. S. C. A., Section 333 (a) and (b) as follows:

> (a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.
> (b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 331, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

It is noted that presently immaterial exceptions from punishability are made by subsection (c) of the same section.

"The terms 'drug' and 'label' and 'labeling' are defined by Title 21 U. S. C. A., Section 321, which, among other things, declares that:

> (g) The term "drug" means . . . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or function of the body of man or other animals.
> (k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article.
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article of any of its containers or wrappers, or (2) accompanying such article.

"The definition of misbranding is contained in Title 21 U. S. C. A., Section 352. So far as is pertinent here, it follows:

> A drug . . . . . shall be deemed to be misbranded—
> (a) If its labeling is false or misleading in any particular.
> (f) Unless its labeling bears (1) adequate directions for use;
> (j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.[5]

"By Title 21 U. S. C. A., Section 371 (a) Congress has declared that:

> The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section,[6] is vested in the Secretary.

"Within that authority, the Secretary has promulgated the following regulation touching the inadequacy of directions for use of drugs (see Title 21 C. F. R. Section 1.106 (a) (1)):

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[5] It will already be apparent that the court does not consider that within the meaning of subsection 352 (j), the drug transported was "dangerous to health" in any reasonably strict meaning of that phrase. Any such danger would seem to arise, if at all, not from the direct effect of the drug, but from its ineffectiveness (see footnote 4, supra).

[6] The exceptions are not material in this proceeding.

1.106 Drugs . . . . . ; directions for use (a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Directions for use in all conditions for which such drug . . . . . is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or in behalf of its manufacturer, packer, or distributor, or in such other conditions, if any there be, for which such drug . . . . . is commonly and effectively used;
(2) Quantity of dose (including quantities for persons of different ages and different physical conditions);
(3) Frequency of administration . . . . . ;
(4) Duration of administration . . . . . ;
(5) Time of administration . . . . . (in relation to time of meals, time of onset of symptoms, or other time factor);
(6) Route or method of administration. . . . .
(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

"The court does not understand the government to contend that any of the several newspaper advertisements should be considered within the definition of 'labeling.' It is not so charged in the information. The contention is that those advertisements, sponsored, and wholly or partly paid for by the defendants, constitute recommendations or suggestions by the defendants themselves of conditions for the use of the drugs, and, therefore, are entitled to be considered in determining whether the directions for their use are inadequate within the definition of Title 21 C. F. R., Section 1.106, supra. The court regards that contention as well taken. Thus limited, it is not necessary to prove, nor is it averred in the information, that any such advertising (or the material thereof or plates or mats therefor) accompanied the drug or any shipment thereof, within the meaning of Title 21 U. S. C. A., Section 321 (m), supra. Indeed, the defendants are not charged with the 'introduction or delivery for introduction into interstate commerce' of any such advertising material or of the equipment for it.

"It is charged, and as the court considers fully proved, that the several display posters 'accompanied' the drugs within the intendment of Title 21 U. S. C. A., Section 321 (m). Upon that premise, and regard being had to its language and actual and intended use, each such poster constituted 'labeling' of the drug. That the posters accompanied the drugs seem to be conclusively settled. *Kordel* v. *United States* 335 U. S. 345 (affirming *United States* v. *Kordel* (7 cir) 164 F (2) 913); *United States* v. *Urbuteit* 335 U. S. 355; *United States* v. *Kaadt* (7 Cir.) 171 F (2) 600; *Alberty Food Products* v. *United States* (9 cir) 194 F (2) 463. They were shipped by the defendants to the consignees of shipments of the drugs as a part of the defendants' program for the marketing of their product and, though not in the same packages, or even at the identical time with the drugs themselves, at such times as were calculated to further the sales to ultimate consumers of the drugs. No more is required for 'accompaniment.' Upon this subject the cited opinions, supra, are conclusive. This is particularly true of *Kordel* v. *United States*, *supra*, which is given an added significance by a dissenting opinion that serves to emphasize the full consideration which the issue received. In the majority opinion, Mr. Justice Douglas says:

> In this case the drugs and the literature had a common origin and a common destination. The literature was used in the sale of the drugs. It explained their uses. Nowhere else was the purchaser advised how to use them. It constituted an essential supplement to the label attached to the package. Thus the products and the literature were interdependent, as the Court of Appeals observed.
>
> It would take an extremely narrow reading of the Act to hold that these drugs were not misbranded. A criminal law is not to be read expansively to include what is not plainly embraced within the language of the statute (*United States v. Resnick*, 299 U. S. 207; *Kraus & Bros.* v. *United States* 327 U. S. 614, 621–622), since the purpose fairly to apprise men of the boundaries of the prohibited action would then be

defeated. *United States* v. *Sullivan* 332 U. S. 689, 693; *Winters* v. *New York* 333 U. S. 507. But there is no canon against using common sense in reading a criminal law, so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it. See *Roschen* v. *Ward* 279 U. S. 337, 339.

"Without needless emphasis, it may be observed that the opinion's thought touching a common sense approach to construction may be given effect in appraising the present defendants' argument, fortified by the citation of *Alberty* v. *United States* (9 cir) 159 F (2) 278, for a more strict construction here of the cited sections of Title 21 U. S. C. A. than would be allowable if the action were one in forfeiture, or a Federal Trade Commission proceeding. Recognizing the abundant literature which supports a construction of criminal statutes more strict than that accorded in civil actions concerning the same subject, a court must not by narrow construction emasculate an otherwise plain criminal statute. Perversion too often and too easily results from an avowed attempt to construe a legislative enactment either strictly or liberally. The consequence is the distortion of the statute to support a foreordained judicial objective. Legislative language is generally most faithfully construed when it is held to mean simply what it says, read with common sense. See also *Dotterweich* v. *United States* 320 U. S. 277; *United States* v. *One Device, etc.* (10 cir) 160 F (2) 194; and *United States* v. 7 *Jugs of Rakos* (D. C. Minn.) 53 F. Supp. 746. And for a direct consideration of *Alberty* v. *United States*, supra, see *United States* v. *Kordel* (7 cir) 164 F (2) 913 at p. 917.

"A specific criminal intent, an awareness of wrongdoing is not charged against the defendants, or either of them. Nor is it by the cited statute made an essential element of the offenses described in the information. *United States* v. *Dotterweich*, supra; *United States* v. *Kaadt*, supra; *United States* v. *Greenbaum* (3 cir) 138 F (2) 437. See also, though in a condemnation case, *United States* v. *11¼ Dozen Packages, etc.* (D. C. N. Y.) 40 F. Supp. 208.

"The falsity or misleading character of a label or of labeling or of advertising is to be measured by its significance as read by those to whom it appeals. *Aronberg* v. *Federal Trade Commission* (7 cir) 132 F (2) 165; *D. D. D. Corporation* v. *Federal Trade Commission* (7 cir) 125 F (2) 679; *Newton Tea & Spice Co.* v. *United States* (6 cir) 288 Fed. 475; *Charles of the Ritz Distributors Corp.* v. *Federal Trade Commission* (2 cir) 143 F (2) 676; *Bockenstette* v. *Federal Trade Commission* (10 cir) 134 F (2) 369; *Colgrove* v. *United States* (9 cir) 176 F (2) 614 (cert. den. 338 U. S. 911). Counsel for the several parties extensively discuss in their briefs the intellectual level of the prospective customer by which the appeal of such material is to be measured. It seems from the authorities, supra, to be established that the test is neither the significance of the publicity to observers of notably superior intelligence nor its appeal to the mentally dull or infirm, but rather its attraction to people of ordinary understanding and discrimination. The reaction of the average person is thus made the test. But allowance has also to be made for the susceptibility to the publicity of the groups or types of people at whom it is peculiarly aimed. The present drugs and their supporting publicity would have no appeal, and little meaning, to young persons, athletes, high school or university students, or youthful workers or business or professional people. But it is quite otherwise with men and women beyond middle age, the so-called older folk of the type pictured in the challenged newspaper advertising. As most members of the federal judiciary will at once realize, those oldsters need little more than a vagrant suggestion to lead them to hope in the restorative ministry claimed for the defendants' tablets. Their publicity advances a message they are longing to read or hear, and with pathetic eagerness they receive and embrace it. They must especially be regarded in these circumstances, for it is to them and their faltering faculties, physical and mental, that the message of the labeling is oriented. Thus understood, the court has no difficulty in concluding that the labels and labeling are false and misleading. What, indeed, can be more cruelly false and misleading than the inspiration of hope in one for whom actually there is no hope?

"Upon the facts clearly established the court finds and concludes, in connection with each of the three separate shipments of drugs and posters that the labeling therein effected was false and misleading in the several respects

and particulars set out in the information, and, therefore, constituted a misbranding, first, without reference to the newspaper advertising related to the respective shipments. That conclusion alone warrants the conviction of both defendants upon each of the three counts. For it is sufficient to support conviction on the ground of the shipment of a misbranded drug, that the labeling be 'false or misleading in any particular.' Title 21 U. S. C. A., Section 352 (a), in relation to Title 21 U. S. C. A., Sections 321 (a) and 331 (a). *United States* v. *One Device*, supra; *United States* v. *Dr. David Roberts Veterinary Co., Inc.* (7 cir) 104 F (2) 785.

"But the court, secondly, finds and concludes that misbranding of the drugs thus shipped existed in each instance also because of the failure of the labeling to bear 'adequate directions for use,' within the meaning of Title 21 U. S. C. A., Section 352 (b), regard being had to the varied conditions for which the 'drug' was 'prescribed, recommended, or suggested in its labeling' and 'in its advertising . . . . . sponsored by or in its behalf by its manufacturer, packer or distributor,' i. e. the defendants, within the meaning of Title 21 C. F. R. Section 1.106 (a) (1). In the final phase of this conclusion rooted in 'advertising' the court has in view the newspaper advertising received in evidence. That advertising is not itself an offense against the Act denounced in the present information. But it is the defendants' own 'recommendation and suggestion' respecting the use of the drug, by which in part the adequacy of the labeling's 'direction for use' is to be appraised.

"It may be stated very briefly that the court does not regard the proceedings in Civil Action No. 79–52, supra, as a defense to the charges against the defendants. Their offense, if any, antedated the prosecution of the civil suit, and was complete long before Case No. 79–52 was commenced. And nothing which occurred in the civil action even assumes to affect the defendants' criminal liability for the earlier shipment of drugs comparable in character to those proceeded against in the civil case.

"The court, therefore, finds and adjudges the defendants, and each of them, to be guilty as charged, and convicts the defendants, and each of them, of the charges against them, in each of the three counts of the information.

"Concerning the sentence to be pronounced, it is considered that only the opening portion of Title 21 U. S. C. A., Section 333 (a), has present application. No situation drawn to the court's attention would warrant resort to the more severe provision of subsection (a) or to subsection (b) of the same section. The maximum allowable sentence for each defendant under each count is, therefore, imprisonment for not more than one year (applicable, of course, only to an individual defendant) or a fine of not more than $1,000.00 or both such imprisonment and fine. Maximum sentences ought rarely to be resorted to unless the circumstances of the offense are aggravated. Whatever the facts may be, no aggravating features of the offenses under prosecution have been established.

"The court has resolved to, and does, sentence the defendant, Vitamin Industries, Inc., to pay a fine of $150.00 upon each of the three counts of the information (in all $450.00) and, in addition thereto, the costs of this action, and the defendant Joseph L. Zweiback to pay a fine of $50.00 upon each of the three counts of the information (in all $150.00). No sentence to imprisonment is imposed or considered to be warranted."

4585. Anterior pituitary aqueous extract. (F. D. C. No. 37041. S. No. 83–979 L.)

QUANTITY: 36 cartoned vials at Minneapolis, Minn.

SHIPPED: Between 2–25–54 and 4–9–54, from Indianapolis, Ind., by Pitman-Moore Co.

LABEL IN PART: (Vial) "10 cc. Size Parenteral Solution Extract of Anterior Pituitary Aqueous Each cc. contains the water soluble extractive from 18½ grs. of fresh anterior pituitary. Chlorobutanol (chloral deriv.) 0.5% (Preserv.). Caution: To be dispensed only by or on the prescription of a veterinarian. Warning: Contains no known therapeutically active principle derived from anterior pituitary for which recognized methods of assay exist."

LIBELED: 8–11–54, Dist. Minn.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 11–3–54. Default—destruction.

4586. Ovarian tissue extract. (F. D. C. No. 37030. S. No. 40–257 L.)

QUANTITY: 137 8-cc. vials at Phoenix, Ariz.

SHIPPED: 6–3–54, from Los Angeles, Calif., by American Bio-Chemical Corp.

LIBELED: 8–18–54, Dist. Ariz.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 11–24–54. Default—destruction.

4587. Glanosol. (F. D. C. No. 36833. S. No. 80–545 L.)

QUANTITY: 135 unlabeled 30-cc. vials in bulk containers at Philadelphia, Pa.

SHIPPED: 5–20–54, from Inwood, Long Island, N. Y., by Bel-Mar Laboratories, Inc.

LABEL IN PART: (Bulk container) "No. 419V30 Multiple Dose * * * Glanosol Each 2 cc. contains the water soluble extractives of dried glands derived from fresh glands equivalent to: Adrenal Cortex . . . 1½ gr. Ovarian . . . 16 gr. Anterior Pituitary. . . . 5 gr. Thyroid (dried) . . . . 1 gr. Thymus . . . . 3 gr. Lymphatic . . . . 2 gr. Chlorobutanol (chloral deriv.) . . . . 0.5% Water . . . . q. s. * * * For intramuscular Use * * * There is no scientific evidence for the presence of therapeutically active principles in the aqueous glands listed, with the exception of thyroid. * * * Caution: Federal law prohibits dispensing without prescription."

LIBELED: 6–16–54, E. Dist. Pa.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use.

DISPOSITION: 9–28–54. Default—destruction.

4588. Urasal. (F. D. C. No. 36236. S. Nos. 45–946/7 L.)

QUANTITY: 19 cartons, 1 3½-oz. btl. each, and 26 cartons, 1 10-oz. btl. each, at Manchester, N. H.

SHIPPED: 7–27–53, from San Juan, P. R., by Horner Laboratories, Inc.

LABEL IN PART: (Btl.) "Urasal * * * Granular Effervescent Contains: Methenamine, Piperazine, and Benzoic Acid in Proportionate Combination."

RESULTS OF INVESTIGATION: Examination indicated that the article consisted essentially of methenamine in an effervescent base.

LIBELED: 1–15–54, Dist. N. H.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use since its labeling failed to state the condition or conditions for which the article was intended.

DISPOSITION: 12–13–54. Claimed by Horner Laboratories, Inc., and subsequently destroyed.

4589. Madam Wilder's Southern Herbs. (F. D. C. No. 37012. S. Nos. 86–332/3 L.)

QUANTITY: 683 16-oz. btls. at Cleveland, Ohio.

SHIPPED: During March, April, and May, 1954, from Detroit, Mich., by Gerald A. Stewart, d/b/a Vittonic Co.

RESULTS OF INVESTIGATION: Analysis showed that the product contained approximately 30.0 grams per 100 cc. of epsom salt, 0.8 gram per 100 cc. of sodium salicylate, saccharin, oil of clove, sodium phosphate, oil of peppermint, ferric and ammonium citrate, sodium bicarbonate, and oil of sassafras. Plant extractives other than volatile oils were not detected.

LIBELED: 7–19–54, N. Dist. Ohio.

CHARGE: 502 (a)—the bottle label of the article when shipped contained false and misleading representations that the article would be effective in the treatment of headaches, arthritic and rheumatic pains, indigestion, colds, constipation, coated tongue, impure blood, tired, dull, weak feelings, gastritis, and kidney trouble; and, 502 (f) (2), the article was essentially a laxative, and its labeling failed to bear a warning that frequent or continued use of the article may result in dependence on laxatives to move the bowels.

DISPOSITION: 10–1–54. Consent—destruction.

4590. EE-Sterilizer device. (Inj. No. 285.)

COMPLAINT FOR INJUNCTION FILED: 1–18–55, against Clarence E. Farris, t/a Igwtee and Igwt, at Truth or Consequences, N. Mex., to enjoin the interstate shipment of the above-mentioned device, which was misbranded.

ACCOMPANYING LABELING: Circulars entitled "This is the Famous EE Sterilizer," "Electronics Kill Diseases In The Body," "The New Twin Sisters," and "This Is That Professional Model."

CHARGE: The complaint alleged that the device consisted of a small radio transmitter which would give off radio waves of weak intensity when connected to an electrical outlet; that the defendant was engaged in selling and distributing in interstate commerce various models of the device, which were variously designated as "Hospital Model EE–Sterilizer Number H–109," "Cancer Research Model EE–Sterilizer Number HC–84," "Hospital Model EE–Sterilizer Number H–117," "Professional Model EE Sterilizer Model C," "EE Sterilizer Model B," "The New Twin Sisters Hospital Model H," and "Cancer Research Model–HC;" and that the device was misbranded as follows:

502 (a)—the accompanying labeling of the device contained false and misleading representations that the device was an adequate and effective treatment for bacterial infection, virus infection, poliomyelitis, sinus infection, prostate conditions, ear infections, tooth infections, infected tonsils, hand infection, colds, influenza, dysentery, sores, asthma, pimples, venereal disease, and all other infections of the body.

The complaint alleged further that if the defendant was forced by an injunction to refrain from using the existing labeling on interstate shipments of the device, the defendant would not discontinue interstate distribution of the device, but would, unless enjoined, continue to ship the device in interstate commerce without labeling stating the conditions and purposes for which the device was intended; and that in such case, the device would be misbranded under 502 (f) (1) in that its labeling would fail to bear adequate directions for use because of the omission from its labeling of statements of the conditions and purposes for which the device was intended.

The complaint alleged also that the defendant was well aware that his activities were violative of the Act; that he had been warned by a Notice of Hearing dated 7–27–53, and, in subsequent correspondence from the Food and Drug Administration, that the device was misbranded by the false and misleading statements in the accompanying labeling; and that despite such warnings, the defendant continued to introduce the misbranded device into interstate commerce.

DISPOSITION: 2–10–55. The defendant having consented, the court entered a decree of injunction perpetually enjoining the defendant from introducing into interstate commerce the *EE–Sterilizer device* or any other device of similar construction which was misbranded under 502 (a) or 502 (f) (1).

4591. Super Zone device. (F. D. C. Nos. 36542, 36544. S. Nos. 86–127/8 L.)

QUANTITY: 2 devices at Fort Collins, Colo.

SHIPPED: 11–14–52, from Los Angeles, Calif., by Super Zone Co.

LABEL IN PART: "Super Zone Co. Los Angeles, Calif. Model No. B Serial No. 123 [or "126"] 120 Volts 60 Cycles 2.0 Amperes."

ACCOMPANYING LABELING: Leaflet entitled "Connecting The Superzone Instrument."

RESULTS OF INVESTIGATION: In the operation of the device, oxygen was passed through the device, and the effluent gas, which included some ozone, produced by electrical discharge in the device, would leave the generating chamber through a hose attached to the applicator.

LIBELED: 5–4–54, Dist. Colo.

CHARGE: 502 (a)—the labeling of the device when shipped contained false and misleading representations that the device provided an adequate and effective treatment for infected sinus, asthma, sore throat, vaginitis, cervicitis, and internal hemorrhoids; and 502 (f) (1)—the labeling failed to bear adequate directions for use.

DISPOSITION: Theodore T. Josephson, t/a Super Zone Co., appeared as claimant. Pursuant to a stipulation entered into between the claimant and the United States attorney, the court, on 6–18–54, ordered that the action be removed to the United States District Court for the Northern District of California for trial.

On 7–23–54, the claimant filed an answer denying that the devices were misbranded as alleged. On 12–9–54, the claimant having filed a stipulation for the withdrawal of his claim and answer, the court entered a decree condemning the devices and ordering that they be permanently released to the custody of the Food and Drug Administration.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4592. Pecan oil. (Inj. No. 266.)

COMPLAINT FOR INJUNCTION FILED: 7–8–54, N. Dist. Tex., against three corporations, namely, the Planters Cotton Oil Co., Weatherford Oil Refining and Distributing Co., and J. R. Fleming & Co., Inc., of Weatherford, Tex., and James R. Fleming, president of the corporations.

CHARGE: The complaint alleged that the defendants were engaged in the business of manufacturing, preparing, and distributing *pecan oil*, and had been and were, at the time of the filing of the complaint, causing the introduction

and the delivery for introduction into interstate commerce of *pecan oil*, which was adulterated under 501 (a) (1) in that the article consists in part of filthy substances.

The complaint alleged that the *pecan oil* was manufactured from material which consisted of pecan meats, pecan shells, curculio larvae, coleoptera insects, floor sweepings, broom straws, cigarette butts, pieces of paper, and burnt matches, and that examination disclosed that the *pecan oil* contained a mixture of pecan oil, curculio larvae oil, and oil soluble extractives from insects, cigarette butts, and other extraneous material.

The complaint alleged also that the defendants had in their possession a quantity of adulterated *pecan oil* which would in the usual and ordinary course of business be shipped in interstate commerce. The complaint alleged further, on information and belief, that the defendants would continue to introduce and cause to be introduced and deliver and cause to be delivered into interstate commerce adulterated *pecan oil* unless restrained by the court.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 7–8–54, the court entered a temporary restraining order enjoining the defendants from introducing or causing to be introduced or delivering or causing to be delivered, for introduction into interstate commerce, *pecan oil* adulterated as alleged in the complaint. On the same date, an order was entered directing the defendants to show cause why a preliminary injunction should not issue. On 7–16–54, with the consent of the defendants, a preliminary injunction was issued pending a hearing on the merits.

On 11–18–54, the defendants having consented in the entry of a decree, the court entered a decree perpetually enjoining and restraining the defendants from directly, or indirectly, introducing or causing to be introduced, or delivering or causing to be delivered, for introduction into interstate commerce, *pecan oil*, or any other such article which was adulterated as alleged in the complaint. The decree provided further that the defendants be perpetually enjoined and restrained from directly, or indirectly, introducing or causing to be introduced, or delivering or causing to be delivered, for introduction into interstate commerce, any stock on hand of *pecan oil* adulterated within the meaning of 402 (a) (3) and 501 (a) (1).

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4593. Various drugs. (Inj. No. 260.)

COMPLAINT FOR INJUNCTION FILED: 3–19–53, S. Dist. Ill., against Schlicksup Drug Co., Inc., Peoria, Ill., to enjoin the interstate shipment of adulterated and misbranded drugs.

CHARGE: The complaint alleged that the defendant was engaged in manufacturing, selling, and introducing into interstate commerce various drugs which were adulterated within the meaning of 501 (c), and misbranded within the meaning of 502 (a).

The complaint alleged further that the adulterated and misbranded condition of the drugs resulted from deficiencies in the ingredients of the drugs and the presence of ingredients in amounts in excess of those declared on the label. For example, defendant's "Triple Sulfas Alkaline" labeled as con-

*See also No. 4583.

taining in each fluid ounce "Sulfadiazine 15 grs. Sulfamerazine 15 grs. Sulfamethazine 15 grs." contained 32 percent less than the declared amount of total sulfas, and the article contained no sulfamethazine; the "Elixir D. Desoxyephedrine Alcohol" contained 7 percent less d-desoxyephedrine hydrochloride and 60 percent less alcohol than labeled; the "Vitamin B Elixir" contained 22 percent less vitamin B_1 than declared on the label; the "Acephenacil No. 5 * * * Acetylsalicylic Acid 2 Grs." contained 24 percent less aspirin than labeled; the "Elixir Thiobrombarb" contained 29 percent less potassium bromide, 25 percent less potassium sulfocyanate, and 18 percent less alcohol than declared on the label; some of the "Triple Sulfas Alkaline" contained 26 percent more than the labeled amounts of total sulfas; and the "Elixir Phenobarbital and Bromides" was 12 percent deficient in bromides and 18 percent deficient in alcohol.

The complaint alleged further that the defendant was well aware that its activities were violative of the Act. Inspections were made of the defendant's plant at Peoria, Ill., by inspectors of the Food and Drug Administration seven different times between 8–8–52 and 1–9–53, at which times the defendant was informed of the lack of control over the manufacturing, packaging, and labeling of the drugs and of the confusion and disorder existing in the plant which would result in errors of composition and labeling; and warned that such conditions also would result in the drugs being adulterated and misbranded. On 11–13–52, the shipment of "Acephenacil No. 5 * * * Acetylsalicylic Acid 2 Grs.," previously referred to, was seized and condemned and ordered destroyed.

The complaint alleged also that despite the warnings conveyed to the defendant by the plant inspections and the seizure, the defendant continued to introduce into interstate commerce adulterated and misbranded drugs.

DISPOSITION: On 3–19–53, a temporary restraining order was entered enjoining the defendant against the interstate shipment of adulterated and misbranded drugs. The matter came on for hearing before the court on 3–25–53, and at the conclusion of the testimony, the matter was taken under advisement by the court pending the submission of briefs by counsel.

On 10–21–53, the court handed down its findings of fact and conclusions of law and, in accordance therewith, entered an order for a temporary injunction. The injunction enjoined the defendants during the further pendency of the suit or until further order of the court from introducing into interstate commerce drugs adulterated because their strength differed from that which they were represented to possess, or misbranded because of false and misleading statements in the labeling of the drugs with respect to the quantity of ingredients contained therein.

4594. Ocu-Lav eyewash. (F. D. C. No. 36898. S. No. 50–450 L.)

QUANTITY: 12 cases, each containing 25 cartoned btls., at New York, N. Y.

SHIPPED: 6–16–54, from Jersey City, N. J., by G & W Laboratories, Inc.

LABEL IN PART: (Ctn. and btl.) "Feel it Work! Ocu-Lav Eye Wash * * * Active Ingredients Natural Oils of Wintergreen and Eucalyptus, Sodium Borate, Menthol, Thymol, Boric Acid."

LIBELED: 7–19–54, S. Dist. N. Y.

CHARGE: 501 (c)—the purity and quality of the article when shipped fell below that which it was represented to possess since it was for use in the eyes and was contaminated with living micro-organisms; and, 502 (a)—the bottle

and carton label contained false and misleading representations that the article was effective in the treatment of sties, granulation, inflammation and congestion of the eyes and eyelids, and conjunctivitis.

DISPOSITION: 9–20–54. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4595. C-Tone. (F. D. C. No. 36608. S. Nos. 26–473 L, 26–489 L.)

INFORMATION FILED: 10–29–54, S. Dist. N. Y., against Balanced Foods, Inc., New York, N. Y., and Samuel H. Reiser, secretary and treasurer of the corporation.

SHIPPED: Between 9–30–53 and 11–4–53, from New York to Pennsylvania.

LABEL IN PART: (Btl.) "Rich in Activated Enzymes C-Tone The *Natural* Vitamin C Tonic * * * 8 Fl. Oz Net Sole and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

ACCOMPANYING LABELING: Leaflets entitled "Which of These Dread Killers Threaten Your Advancing Years?"

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article would be of nutritional and therapeutic value because of its enzyme content; that it would be effective as a tonic; that it would be an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells; and that it would be effective to provide energy.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 5–27–55, and at the conclusion of the trial, the case was taken under advisement for consideration of the briefs of counsel with respect to the defendants' motion for dismissal of the information. On 6–23–55, the court sustained the defendants' motion in accordance with the following opinion:

REEVES, *District Judge:* "The defendants are charged in two counts with having shipped a misbranded food product in interstate commerce in different periods during the year 1953. The product complained against was entitled 'C-Tone.' This product was represented to contain valuable and important nutrients. It is admitted that the product thus shipped in interstate commerce was misbranded and that it fell within the prohibitions of section 321, Title 21 U. S. C. A., relating to the general subject of Food and Drugs.

"While acknowledging that the product was misbranded within the purview of the law, yet defendants urged as a defense a reliance upon that portion of section 331, Title 21 U. S. C. A. and the exception set out therein by paragraph (h) and by paragraph (c) of section 333, of said title. It is provided by pertinent provisions of section 331, Title 21 U. S. C. A. as follows:

> The following acts and the causing thereof are hereby prohibited:
> * * *
> (h) The giving of a guaranty or undertaking referred to in section 333 (c) (2), which guaranty or undertaking is false, except by *a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith, the food, drug, device, or cosmetic;* * * *. [Emphasis mine.]

*See also Nos. 4581–4584, 4589–4591, 4593, 4594.

It will be noted from the foregoing that the giving of a false guaranty is prohibited, but there is no prohibition against one who in good faith receives a product backed by a full guaranty.

"Section 333 provides penalties for the violation of section 331, and it is to be noted that one found guilty of shipping in interstate commerce misbranded food or food products may be imprisoned not exceeding one year or be subject to both such imprisonment and fine.

"By paragraph (c) of said section 333, it is provided:

> No person shall be subject to the penalties of subsection (a) of this section * * * (2) for having violated section 331 (a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received *in good faith* [emphasis mine] the article, * * *.

At the trial of the case the defendants submitted a guaranty from a responsible producer, as contemplated by the several sections of the statutes, and the defendants strongly asserted their good faith in receiving said product because of said guaranty. Before the shipments in question were made, the defendants were advised of the contention made by government agents and agents of the City of New York, that the product was misbranded and in fact some of the merchandise held by the defendants was seized by said agents. The defendants communicated these facts to the guarantor and were given assurances that the charge was a mistake and that, if necessary, a slight change would be made in the labels as well as in the company's literature, so as to satisfy the government through its agents. With these assurances the defendants continued to deal in the product and to make shipments.

"It is now the contention of counsel for the government that the seizures made by local and national authorities were sufficient to advise the defendants of the misbranding, and to justify or warrant this prosecution.

"1. It is to be noted that the gravamen of the offense is the alleged bad faith on the part of defendants at the time they received the merchandise or product. While it is the government's contention that such bad faith would follow the complaints or seizures by the authorities, and that, after such complaints, and after such seizure, any product received by the defendants must be received in bad faith or, rather, not received in good faith.

"2. The testimony of the defendant Samuel H. Reiser, who spoke for himself as well as for the corporate defendant, indicated that he was reassured by the guarantor and that he believed sincerely that he had a right to continue the shipment of the product in interstate commerce. Moreover, it is the law that the acts and words of the agents of the government were not such notice to him as would warrant him and the corporate defendant in desisting from further shipment of the product.

"3. There are many cases which, by analogy, would not make an individual subject to punishment merely because of the acts of municipal agents, whether arbitrary or otherwise. The defendants, in the transaction of their business handling, as the testimony indicated, from 1500 to 2000 different products would undoubtedly have a right, with such assurances as were given in this case, to proceed in the transaction of their business until there was such an adjudication or authorative determination that the merchandise was misbranded as to bring home to them definite knowledge of the fact that by such shipments they were in fact violating the law. It should be noted and emphasized that the statute provides an exemption if and when the merchandise or product is received in good faith.

"4. In good faith has several meanings, each of which is well defined. It means, among other things, honesty and in an attitude of trust and confidence.

"The evidence justifies the court in believing that the personal defendant, who acted for the corporate defendant at all times in receiving the product, was actually in an attitude of trust and confidence, and in such trust and confidence the shipments complained against were made.

"It would follow that the motion for an order directing acquittal should be sustained, and IT IS SO ORDERED."

4596. Muscle-Aid. (Inj. No. 258.)

PETITION FILED: On 4–12–54, in the S. Dist. Calif., the United States Attorney filed a petition for an order to show cause why Herman H. Kronberg, doing business under the name of Muscle-Aid Co., Los Angeles, Calif., should not be punished for criminal contempt of the permanent injunction which had been entered against him on 1–6–53 (notice of judgment on drugs and devices, No. 4046).

CHARGE: The petition alleged that, following the entry of the injunction, the defendant engaged in a nationwide distribution of a drug which he marketed under the name of *Muscle-Aid* and offered to the public as effective in the treatment of six of the prohibited conditions listed in the injunction, namely, arthritis, rheumatism, neuralgia, sciatica, sprains, and bruises; that *Muscle-Aid* was identical in composition with Muscle-Rub, the specific product involved in the original injunction proceeding, except that 1-oz. of turpentine per gallon was added to the Muscle-Rub formula to produce *Muscle-Aid;* that the limited therapeutic properties of each article were essentially the same; and that the articles were "similar" as that term was used in the injunction.

The petition further alleged that the defendant had caused interstate shipments of *Muscle-Aid* to be made from Los Angeles, Calif., to Hanover, Pa., and Birmingham, Ala., on 10–1–53 and 10–12–53; that, when so shipped, the article was misbranded under 502 (a) in that its labeling, when read in the light of the promotional setting, created the false and misleading impression in the mind of the prospective purchaser that the article was efficacious for the relief and cure of pains due to arthritis, rheumatism, neuralgia, sciatica, sprains, and bruises; and, that by reason of the shipments, the defendant was in criminal contempt of the permanent injunction.

DISPOSITION: On 4–12–54, the order to show cause was issued, and on 6–21–54, the defendant pleaded guilty to violation of the injunction. On 7–12–54, the court suspended sentence and placed the defendant on probation for 5 years on condition (1) that he pay to the Government $1,000 in such manner and in such amounts as the probation officer should prescribe; (2) that he should not engage in any business under the jurisdiction of the Food and Drug Administration, except with the expressed written permission of the probation officer; and, (3) that during the period of probation, the defendant should not violate any of the laws of the United States or of the State of California.

4597. Muscle-Aid. (F. D. C. No. 36185. S. No. 83–392 L.)

QUANTITY: 86 doz. 3-oz. btls. and 20 doz. 8-oz. btls. at Madison, Wis.

SHIPPED: Between 3–25–53 and 4–27–53, from Los Angeles, Calif., by Muscle-Aid Co.

LABEL IN PART: (Btl.) "Muscle-Aid Use as an aid in the Relief of Pain and discomfort from Rheumatism, Arthritis, Neuralgia, Sciatica, & Sprains, Sore Muscles * * * Contents: Isopropyl Alcohol . . . . 75% Ethyl Alcohol . . . . 1.8% Methyl Salicylate, Camphor, Oil of Turpentine, Menthol & Fld. Ext. Hamamelis."

ACCOMPANYING LABELING: Leaflet entitled "Muscle-Aid."

RESULTS OF INVESTIGATION: To establish a setting in which the labeling statements would be read by the consumer, the shipper caused to be supplied advertising mats for advertising in a Madison, Wis. newspaper. These mats pictured for contrast a gnarled, deformed hand of a person suffering from arthritis

deformans and a hand in normal condition, and contained the statement in bold type "Rheumatism, Arthritis Pains Relieved in a few minutes with Doctor's External Prescription," followed by various statements and testimonials with respect to the use of the article in various diseases and conditions.

LIBELED: 12–10–53 W. Dist. Wis.

CHARGE: 502 (a)—the labeling of the article when shipped was false and misleading because, when read in the light of the setting in which it was intended to be read, it conveyed to the public a meaning which represented and suggested that the article was more than a palliative relief for simple muscular pains and that it was an adequate and effective treatment for arthritis, rheumatism, neuralgia, sciatica, sprains, and bruises, whereas the article was not an adequate and effective treatment for arthritis, rheumatism, neuralgia, sciatica, sprains, and bruises.

DISPOSITION: 12–2–54. Default—destruction.

4598. **B-amino-complex tablets.** (F. D. C. No. 34608. S. Nos. 9–368/9 L.)

QUANTITY: 772 100-tablet btls. at Chicago, Ill.

SHIPPED: Between 6–26–52 and 7–12–52, from New York, N. Y., by Unitone Corp.

LABEL IN PART: (Btl.) "100 Tablets B-Amino-Complex (or B-Amino BAC-Complex) A brand of amino acids, coenzymes, vitamins and minerals Daily dose of 6 tablets contains: Vitamin B_1 (Thiamine Hydrochloride) 18.0 mg. Vitamin B_2 (Riboflavin) 27.0 mg. Niacinamide 180.0 mg. Vitamin B_6 (Pyridoxine Hydrochloride) 3.0 mg."

ACCOMPANYING LABELING: Display cartons marked "BAC"; leaflets headed "If Your Body Could Talk It Would Say"; placards entitled "For The One In Five Who Is Hard Of Hearing"; and folders entitled "A Revolutionary Advance In Nutrition."

LIBELED: 1–19–53, N. Dist. Ill.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness and irritability; that it would supply energy to the heart, lungs, muscles, liver, and other important organs; that it would supply missing enzymes necessary to carry on body functions, such as growth, reproduction, secretion, nerve condition, and muscular contraction; that it would stimulate the body to work as nature intended; that it would endow the user with vibrant life, health, and energy; that it would enable the liver to convert more than normal amounts of carbohydrates into energy; that it would transfer fatigue to quick energy; that it would prevent and correct disfunction in the energy conversion chemistry of body functioning; that it would reactivate all enzymes systems necessary for healthy body functioning; that it would activate the body cells to function as nature intended; and that it would supply needs that are missing from the food one eats.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 8–14–53. Default—destruction.

4599. **Polorator device.** (F. D. C. No. 35584. S. Nos. 33–208 L, 58–891 L, 58–898 L.)

INFORMATION FILED: 10–27–54, W. Dist. Mich., against Edwin M. Vogt, t/a Vogt Health Appliance Co., Kalamazoo, Mich.

SHIPPED: Between 9–30–53 and 12–4–53, from Michigan to Illinois and Indiana.

ACCOMPANYING LABELING: Leaflets entitled "The Polorator Application and Instructions," "Only the Polorator has Twin Pole Vibrators with Soothing Heat," "This is a distributors' confidential bulletin," "An Entirely New Low Priced Instrument for Beauticians," charts bearing the words "Zone Therapy Chart," books entitled "Stories the Feet Can Tell," and display placards reading in part "Free Massage over these areas," "Try Now! this 3 Minute Test," "The Polorator World's Most Flexible Massager," "Polorator, Double action massage with mild heat."

RESULTS OF INVESTIGATION: Each device was found to consist essentially of a housing containing electromagnetic coils that would operate two vibrating metal knobs protuding from the housing.

CHARGE: 502 (a)—the labeling of the device when shipped contained false and misleading representations that the device would provide an adequate and effective treatment for all ailing conditions, chronic conditions, eyestrain, migraine headaches, sore gums, bronchitis, gas pains, ulcers, constipation, summer complaint, prostate trouble, female trouble, nervous and physical tensions, sinus conditions, arthritis, neuritis, overweight, fibrous swelling or infiltration in the interior of the body, bony or cartilaginous growth in the joints, tired, droopy feeling, poor circulation, aching joints, bursitis, kidney conditions, gallbladder conditions, muscular and organic disturbances, hay fever, asthma, congestion of the appendix, ileocecal valve conditions, pneumonia, conditions affecting the spleen, anemia, glaucoma, deafness, sore throat, enlarged tonsils, thyroid conditions, exophthalmic goiter, glandular trouble, enlarged prostate, diabetes, eczema, heart conditions, liver conditions, varicose veins, Bright's disease, dropsy, lumbago, apoplexy, rectal disorders, hemorrhoids, prolapsed rectum, and inflammation of the bladder.

PLEA: Guilty.

DISPOSITION: 1–27–55. Defendant fined $500 and placed on probation for 2 years.

DRUGS FOR VETERINARY USE

4600. Veterinary drug preparations. (F. D. C. No. 35573. S. Nos. 20–645/9 L, 64–431 L.)

INFORMATION FILED: 11–4–54, E. Dist. Wis., against Dr. David Roberts Veterinary Co., Inc., Waukesha, Wis., and Frank L. Roberts, president.

SHIPPED: Between 2–26–52 and 5–1–53, from Wisconsin to Minnesota and Oregon.

LABEL IN PART: (Carton) "Dr. David Roberts Diuretic Prescription No. 84 [or "Special Rx No. 63 For Livestock at Breeding Time"]," "Dr. David Roberts Herd Iron Tonik for Cows [or "Sheep"]," "Dr. David Roberts Worm Seed Rx No. 89," and "Dr. David Roberts Udder Rx No. 20 for Cows An Aid In the Treatment of Mastitis."

ACCOMPANYING LABELING: Leaflets entitled "Full Line of Veterinary Medicines"; booklets entitled "The Practical Home Veterinarian"; leaflets entitled "Take Good Care of Your Livestock and Your Livestock Will Take Care of You"; and booklets entitled "The 1953 Cattle Specialist."

CHARGE: 502 (a)—the accompanying labeling of the articles when shipped contained false and misleading representations that *Diuretic Prescription No. 84* was an adequate and effective treatment for faulty kidney action in all animals, red water in cattle, azoturia or paralysis of the hind parts, and

kidney disease in horses; that *Special Rx No. 63 For Livestock at Breeding Time* was an adequate and effective treatment for breeding troubles of cows, mares, and sows; for slow breeders or failure to conceive in cows; for slow breeding or failure to conceive in mares; and for abortion ("Sows Losing Pigs") in sows; that it would stimulate breeding in cows, mares, and sows, and would act as a tonic and a regulator for the genital organs of livestock; that *Herd Iron Tonik for Cows* was an adequate and effective treatment for cows not doing well, overworked cows, eye diseases, fistula, genital organ disorders, superficial itch and skin diseases such as eczema and mange, lump jaw or actinomycosis, warts of cattle, calf scours in nursing calves when administered to the cows, inflammation of the testicles of bulls, and sleeping sickness in horses; and that it was an adequate and effective preventive against bloat and ketosis (acetonemia) in cattle and would restore cattle to a normal, healthy condition regardless of the condition before using, keep herds of cattle profitable, healthy, and producing at top quality, aid digestion, tone up the system, promote vigor, build up the quality of the blood, and restore a normal flow of milk in cows; that *Herd Iron Tonik for Sheep* was an adequate and effective treatment for catarrhal fever and colds, indigestion, pregnancy, lambing disease, foot rot, and lung worms, and that it would restore nervous, rundown, or unthrifty sheep to a normal, healthy condition, and would keep flocks of sheep profitable; that *Worm Seed Rx No. 89* was an adequate and effective treatment for removing bots from horses and all species of worms from livestock and poultry; and that *Udder Rx No. 20 for Cows* was an adequate and effective treatment for mastitis and other disease conditions of the udders of cows.

The labeling of *Worm Seed Rx No. 89* was also misleading in that the reference on the carton label to the ingredients, American worm seed (chenopodium) and tobacco dust (nicotine), was misleading in that the ingredients were not present in such proportions as to be of therapeutic significance when the article was administered as directed, and in that the article was designated by a name which included the name of one of the ingredients of the article but did not include the names of all of the ingredients.

PLEA: Guilty.

DISPOSITION: 2–7–55. Corporation fined $1,500; individual fined $200.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4581 TO 4600

PRODUCTS

[1] (4581, 4590, 4592, 4593, 4596) Injunction issued.
[2] (4595) Prosecution contested. Contains opinion of the court.
[3] (4591) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4581, 4590, 4592, 4593, 4596) Injunction issued.
[2] (4595) Prosecution contested. Contains opinion of the court.
[3] (4591) Seizure contested.
[4] (4584) Prosecution contested. Contains opinion and decision of the court.

[1] (4581, 4590, 4592, 4593, 4596) Injunction issued.
[2] (4595) Prosecution contested. Contains opinion of the court.
[3] (4591) Seizure contested.
[4] (4584) Prosecution contested. Contains opinion and decision of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1956

Issued April 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4601–4640

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *April 5, 1956.*

CONTENTS

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4601. (F. D. C. No. 36591. S. Nos. 48–011 L, 48–013/6 L.)

INDICTMENT FILED: 9–30–54, N. Dist. Ala., against **Clyde M. King, t/a Clyde King Drug Co., Birmingham, Ala., and Benjamin H. Darnell (pharmacist).**

CHARGE: Between 9–2–53 and 12–2–53, *penicillin tablets* were dispensed 3 times (counts 1, 2, and 5) and *sulfathiazole tablets* were dispensed two times (counts 3 and 4) without a prescription.

PLEA: Guilty—by King to all counts and by Darnell to counts 1, 4, and 5.

DISPOSITION: 11–5–54. $500 fine against each defendant.

4602. (F. D. C. No. 35567. S. Nos. 15–041/5 L.)

INDICTMENT RETURNED: 5–24–54, W. Dist. Okla., against **Mose Drug, Inc., Lawton, Okla., and Wendell W. Potts and Roy I. Preston (pharmacists).**

CHARGE: Between 9–16–53 and 9–25–53, *sulfathiazole tablets* were dispensed twice (counts 2 and 3), and *sulfadiazine tablets* (count 4), *tablets containing a mixture of sulfadiazine and sodium bicarbonate* (count 1), and *tablets containing a mixture of phenobarbital, acetophenetidin, aspirin, and caffeine* (count 5), were each dispensed once without a prescription.

PLEA: Guilty—by corporation to all counts; by Preston to counts 2, 4, and 5; and by Potts to counts 1 and 3.

DISPOSITION: 7–2–54. Corporation—$1,000 fine; Preston—$225 fine; Potts—$50 fine.

4603. (F. D. C. No. 36666. S. Nos. 88–497 L, 88–508 L.)

INDICTMENT RETURNED: 9–9–54, Dist. Minn., against **Alex H. Altshuler (pharmacist employed at T. E. Sundry Drugs), St. Paul, Minn.**

CHARGE: Between 5–14–54 and 6–15–54, *dextro-amphetamine sulfate tablets* and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–3–55. $500 fine, prison sentence of 2 years suspended, and probation for 5 years.

4604. (F. D. C. No. 35837. S. No. 85–472 L.)

INDICTMENT RETURNED: On or about 9–27–54, Dist. N. Mex., against **Arthur Gilbert (pharmacist for San Antonio Pharmacy), Albuquerque, N. Mex.**

CHARGE: On 12–12–53, *thyroid tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–9–54. $150 fine.

4605. (F. D. C. No. 35611. S. No. 71–680 L.)

INFORMATION FILED: 5–5–55, S. Dist. N. Y., against **Herman W. Litt, t/a Main Street Cut Rate Drug Store, Ossining, N. Y.**

CHARGE: On 7–23–54, *chloral hydrate capsules* were dispensed once by refilling a prescription without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 7–8–55. $250 fine.

4606. (F. D. C. No. 35591. S. Nos. 88-190/1 L.)

INFORMATION FILED: 9-24-54, Dist. Columbia, against **Samuel Joseph Forman, Washington, D. C.**

CHARGE: On 9-23-54, *Ergotrate Maleate tablets* and *capsules containing ergot, apiol, savin oil, and castor oil* were dispensed at the Mayfair Pharmacy, Washington, D. C., without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3-22-55. $100 fine or 30 days in jail.

4607. (F. D. C. No. 36588. S. Nos. 52-239 L, 52-255 L.)

INFORMATION FILED: 11-9-54, S. Dist. N. Y., against **Harry Glazer and Arthur Fitzer (partners in the partnership of Block Drug Store), New York, N. Y.**

CHARGE: Between 11-25-53 and 12-8-53, a prescription for *Gantrisin tablets* was refilled once by Harry Glazer and once by Arthur Fitzer without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 11-23-54. $100 fine against each defendant.

4608. (F. D. C. No. 35785. S. Nos. 41-077 L, 41-079 L, 41-081 L.)

INFORMATION FILED: 7-30-54, Dist. Mont., against **Sophia Hunter Fitzgerald (a partner in the partnership of Fitzgerald's Drug), Browning, Mont.**

CHARGE: Between 8-6-53 and 8-11-53, three drugs, *succinylsulfathiazole with pectin and kaolin (liquid)*, *methamphetamine hydrochloride tablets*, and *tablets of sulfacetamide, sulfamerazine, and sulfadiazine* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-2-54. $175 fine.

4609. (F. D. C. No. 35198. S. Nos. 62-932 L, 62-935/6 L, 62-944 L.)

INFORMATION FILED: 11-12-53, E. Dist. Ill., against **Louis L. Muentefering, t/a Louis L. Muentefering Druggist, East St. Louis, Ill.**

CHARGE: Between 5-15-53 and 5-25-53, *methyltestosterone tablets*, *dextroamphetamine sulfate tablets*, *sulfathiazole tablets*, and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-21-55. $400 fine, plus costs.

4610. (F. D. C. No. 35762. S. Nos. 51-473/4 L.)

INFORMATION FILED: 6-11-54, S. Dist. N. Y., against **Milburne Drug Corp., t/a Comras Drug Co., New York, N. Y., and Julius L. Becker and Jonas Levine (pharmacists for the corporation).**

CHARGE: On 5-4-53 (count 1) and 5-12-53 (count 2), a prescription for *Dexedrine Sulfate tablets* was refilled without authority from the prescriber.

PLEA: Guilty—by corporation and Levine to counts 1 and 2 and by Becker to count 1.

DISPOSITION: 10-6-54, corporation—$100 fine; 10-19-54, Levine—$100 fine; 3-14-55, Becker placed on probation for 1 day and imposition of sentence against him suspended.

4611. (F. D. C. No. 35593. S. Nos. 76–732/36 L, 76–739/41 L.)

INFORMATION FILED: 12–6–54, Dist. Mass., against **Joseph DiGiorgio, t/a Ernst's Drug Store, Boston, Mass.**

CHARGE: Between 5–30–54 and 7–7–54, *Dexedrine Spansules* and *pentobarbital sodium capsules* were each dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–20–55. $400 fine, jail sentence of 6 months suspended, and probation for 2 years.

4612. (F. D. C. No. 35594. S. Nos. 80–855 L, 80–860 L, 80–865/66 L.)

INFORMATION FILED: 12–6–54, Dist. Mass., against **Nicholas Eosco, Boston, Mass.**

CHARGE: Between 5–14–54 and 7–8–54, *Dexedrine Spansules* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–20–55. $400 fine, jail sentence of 6 months suspended, and probation for 2 years.

4613. (F. D. C., No. 35842. S. Nos. 55–865 L, 55–869 L, 55–891/92 L, 55–894 L.)

INFORMATION FILED: 7–29–54, W. Dist. Pa., against **Morris L. Secher, t/a Secher's Pharmacy, Pittsburgh, Pa.**

CHARGE: Between 7–2–53 and 8–5–53, *methyltestosterone tablets* and *secobarbital sodium capsules* were each dispensed once (counts 4 and 5) without a prescription, and *secobarbital sodium capsules* were dispensed 3 times (counts 1, 2, and 3) upon requests for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 3–25–55. $100 fine, plus costs, and probation for 1 year.

4614. (F. D. C. No. 36676. S. Nos. 17–633 L, 17–639 L, 17–643 L, 17–648 L.)

INFORMATION FILED: 12–27–54, S. Dist. Calif., against **Harry Schneiderman (president and pharmacist of Walker Drug Co., Inc.), Los Angeles, Calif., and Samuel S. Freedman, (pharmacist).**

CHARGE: Between 6–10–53 and 8–19–53, *Desoxyn Hydrochloride tablets* were dispensed 4 times (counts 1 to 4, incl.) upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by Schneiderman to counts 1 and 4; not guilty—by Freedman to counts 2 and 3.

DISPOSITION: The case against Freedman came on for trial before the court and jury on 2–8–55, and was concluded on 2–11–55, with the return by the jury of a verdict of not guilty. In the case of Schneiderman, the court, on 2–28–55, sentenced him to serve 3 days in jail and fined him $200.

4615. (F. D. C. No. 36677. S. Nos. 59–487 L, 59–572/5 L, 60–318 L.)

INFORMATION FILED: 4–1–55, E. Dist. S. C., against **Colonial Drug Store (a partnership), Florence, S. C., Duncan S. Farrow (partner and manager), and Ward S. Woodard (clerk for the partnership).**

CHARGE: Between 10–26–53 and 12–4–53, *dextro-amphetamine sulfate tablets* were dispensed 3 times, *sulfisoxazole tablets* were dispensed twice, and *penicillin tablets* were dispensed once without a prescription.

PLEA: Guilty—by partnership and Farrow to all counts of the information and by Woodard to 3 counts involving dispensing of *dextro-amphetamine sulfate tablets* and *sulfisoxazole tablets.*

DISPOSITION: 4–25–55. Farrow—$200 fine; partnership and Woodward—each $100 fine.

4616. (F. D. C. No. 36674. S. Nos. 59–852/53 L, 59–857/58 L, 59–860 L, 60–062 L, 60–064/65 L.)

INFORMATION FILED: 11–29–54, W. Dist. N. C., against **Frank E. Hoey (president of Cleveland Drug Co.), Shelby, N. C., and William O. Britt, Jr. (pharmacist).**

CHARGE: Between 1–8–54 and 1–25–54, *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 3 times (counts 1, 3, and 7), *Dexedrine Sulfate tablets* were dispensed 4 times (counts 2, 4, 5, and 8), and *Metandren Linguets* were dispensed once (count 6) without a prescription.

PLEA: Guilty—by Hoey to all counts and by Britt to counts 3, 4, and 7.

DISPOSITION: 3–22–55. Hoey—$500 fine, jail sentence of 18 months suspended, and probation for 3 years; Britt—$250 fine, jail sentence of 12 months suspended, and probation for 3 years.

4617. (F. D. C. No. 35142. S. Nos. 69–773/4 L, 69–777/8 L, 69–780 L, 69–784 L, 69–786 L, 69–788 L.)

INFORMATION FILED: 10–19–53, Dist. Utah, against **Peter E. Athas, t/a Crystal Pharmacy, Salt Lake City, Utah, and Louis P. Athas (manager of the pharmacy), and Harry C. Fowler (pharmacist).**

CHARGE: Between 5–12–53 and 5–28–53, *methyltestosterone tablets* (counts 1 and 4) were dispensed twice, and *ergonovine maleate tablets* (count 3) and *tablets containing a mixture of sulfathiazole, sulfadiazine, and sulfamerazine* (count 2) were each dispensed once, without a prescription; and *secobarbital sodium capsules* (counts 5 and 6) and *dextro-amphetamine sulfate tablets* (counts 7 and 8) were each dispensed twice upon requests for prescription refills without authorization by the prescribers.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 2–1–54, and at its conclusion, the jury returned a verdict of guilty against Peter and Louis Athas on all 8 counts of the information and against Harry C. Fowler on counts 1, 3, 4, 5, 7, and 8.

On 3–12–54, the court fined Peter and Louis Athas $1,000 and $500, respectively; sentenced both individuals, together with Harry C. Fowler, to prison for 1 year, which sentence was suspended; and placed each of the three individuals on probation for 1 year.

4618. (F. D. C. Nos. 36653, 36656. S. Nos. 52–262 L, 52–266 L, 52–270 L, 52–282 L, 88–978/79 L.)

INFORMATION FILED: 12–6–54, S. Dist. N. Y., against **Louis Gedan, t/a Lemac Community Drug and Lemac Drug, Yonkers, N. Y.; Paul S. Handler (pharmacist for Lemac Community Drug); and William Matz and Horatio D'Orsogna (pharmacists for Lemac Drug).**

CHARGE: Between 10–27–53 and 2–10–54, *dextro-amphetamine sulfate tablets* were dispensed twice and *Oreton-M tablets* were dispensed once without a prescription; and a prescription for *dextro-amphetamine sulfate tablets* was

refilled twice and a prescription for *Amytal Sodium capsules* was refilled once without authorization by the prescribers.

PLEA: Guilty—by Gedan to all charges reported herein; by Handler to the charge of dispensing *dextro-amphetamine sulfate tablets* one time without a prescription; by Matz to the charge of refilling the prescription for *dextro-amphetamine sulfate tablets* one time without authorization; and by D'Orsogna to the charge of refilling the prescription for *dextro-amphetamine sulfate tablets* one time without authorization.

DISPOSITION: 12–13–54. Gedan—$225 fine, imposition of prison sentence suspended, and defendant placed on probation for 1 day; Handler—$25 fine; Matz—$25 fine; D'Orsogna—$25 fine.

4619. (F. D. C. No. 36630. S. No. 59–816 L.)

INFORMATION FILED: 11–8–54, M. Dist. N. C., against **Calvin N. Barger, t/a Barger Drug Store, Oakboro, N. C.**

CHARGE: On or about 10–20–53, *dextro-amphetamine sulfate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 4–19–55. $500 fine.

4620. (F. D. C. No. 36621. S. Nos. 53–813 L, 62–698 L, 63–641/2 L.)

INFORMATION FILED: 10–15–54, S. Dist. Ill., against **John J. Levitt (pharmacist for Dave's Cut Rate Drugs and Liquors), Springfield, Ill.**

CHARGE: Between 3–20–54 and 3–25–54, *dextro-amphetamine sulfate tablets* were dispensed twice and *thyroid tablets* and *tablets containing a mixture of sulfathiazole, sulfadiazine, and sulfamerazine* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–2–55. $100 fine.

4621. (F. D. C. No. 36583. S. Nos. 45–779 L, 45–879 L, 45–887 L, 45–919/20 L, 45–922 L.)

INFORMATION FILED: 8–2–54, Dist. Mass., against **Benjamin Lieberson, t/a Stanley Drug Co., Boston, Mass.**

CHARGE: Between 11–30–53 and 12–17–53, *phthalylsulfacetimide tablets* and *conjugated estrogens tablets* were each dispensed once and *amphetamine sulfate tablets* were dispensed twice without a prescription and *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 10–26–54. $1,200 fine.

4622. (F. D. C. No. 35840. S. Nos. 45–604 L, 45–607 L, 45–783 L, 45–788/89 L, 45–927 L.)

INFORMATION FILED: 8–2–54, Dist. Mass., against **Clarence N. Jackson, t/a Douglass Sq. Pharmacy, Roxbury, Mass.**

CHARGE: Between 11–19–53 and 12–17–53, *conjugated estrogens tablets* were dispensed twice without a prescription, and *sulfisoxazole tablets* and *ampheta-*

mine sulfate tablets were each dispensed twice upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 11-16-54. $100 fine.

4623. (F. D. C. No. 35739. S. Nos. 9-686/7 L, 9-689/90 L.)

INFORMATION FILED: 12-22-53, N. Dist. Ill., against **Sisson Drugs, Inc., Chicago, Ill., and Walter Herman and Edward Holmes (pharmacists).**

CHARGE: Between 2-26-53 and 4-14-53, *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Not guilty by each defendant.

DISPOSITION: 10-19-54. The case came on for trial before the court without a jury, and at its conclusion, the court returned a verdict of not guilty.

4624. (F. D. C. No. 36595. S. Nos. 75-150/1 L, 75-163 L, 75-204 L.)

INFORMATION FILED: 6-9-54, Dist. Columbia, against **Frederick W. Ali, Washington, D. C.**

CHARGE: Between 11-13-53 and 3-15-54, *secobarbital sodium capsules* were dispensed 4 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court without a jury on 11-3-54, and was concluded on the same day, with the return of a verdict finding that the defendant was not guilty by reason of entrapment.

4625. (F. D. C. No. 36596. S. Nos. 76-412/5 L, 76-417/8 L, 76-420 L.)

INFORMATION FILED: 3-18-55, E. Dist. Wash., against **Robert M. Huxsol and Delmer L. Cook (pharmacists for Nevada Street Pharmacy), Spokane, Wash.**

CHARGE: Between 12-18-53 and 1-11-54, *phenobarbital tablets* were dispensed 7 times upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty—by Huxsol to counts 2, 4, 5, and 7, and by Cook to counts 1, 3, and 6.

DISPOSITION: 5-4-55. Huxsol fined $151; Cook, $150.

4626. (F. D. C. No. 35786. S. Nos. 41-071 L, 41-074/5 L.)

INFORMATION FILED: 7-30-54, Dist. Mont., against **James L. Leadbetter (manager of Glacier Drug Store), Browning, Mont.**

CHARGE: Between 8-8-53 and 8-11-53, *penicillin G potassium tablets* were dispensed once and a number of *tablets containing a mixture of dibenzylethylenediamine dipenicillin G, sulfadiazine, sulfamerazine, and sulfamethazine* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9-2-54. $175 fine.

4627. F. D. C. No. 35609. S. Nos. 67-817/20 L.)

INFORMATION FILED: 4-29-55, W. Dist. La., against **Evan R. Flory, t/a Flory's Pharmacy, Bossier City, La.**

CHARGE: Between 9–8–54 and 9–9–54, *penicillin tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5–24–55. Flory fined $300 on count 1; imposition of sentence suspended on counts 2, 3, and 4, and defendant placed on probation for 5 years.

4628. (F. D. C. No. 35601. S. Nos. 67–831/4 L.)

INFORMATION FILED: 4–29–55, W. Dist. La., against **Naremore's Bossier Drug, Inc., Bossier City, La., and James A. Mosley and Charles E. Friend (pharmacists).**

CHARGE: Between 9–8–54 and 9–9–54, *penicillin G potassium tablets* were dispensed 4 times without a prescription.

PLEA: Guilty—by corporation to counts 1 to 4, incl.; by Mosley to counts 1 to 3, incl.; and by Friend to count 4.

DISPOSITION: 5–25–55. Corporation fined $200 on count 1, and Mosley and Friend each fined $100 on counts 1 and 4 respectively; imposition of sentence suspended on counts 2, 3, and 4 as to corporation and on counts 2 and 3 as to Mosley. Defendants placed on probation for 5 years.

4629. (F. D. C. No. 36671. S. No. 75–855 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against **Denali Drug Co., Inc., Anchorage, Alaska, Hugh M. King (president) and Bill W. Deets (pharmacist).**

CHARGE: On 8–28–53, *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty by each defendant.

DISPOSITION: 6–24–55. Corporation fined $350 and each individual fined $50.

4630. (F. D. C. No. 36672. S. Nos. 64–271/2 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against **Rexall Drug Store (a partnership), Anchorage, Alaska, Charles J. Abel (a partner in and manager of the partnership), and Charles W. Barton and Richard C. Cornell (pharmacists for the partnership).**

CHARGE: Between 8–27–53 and 8–29–53, *penicillin G potassium tablets* (count 1) and a quantity of a drug consisting of *dibenzylethylenediamine dipenicillin G, procaine penicillin G, and potassium penicillin G for aqueous injection* (count 2) were each dispensed once without a prescription.

PLEA: Guilty—by partnership, Charles J. Abel, and Charles W. Barton to count 1, and by Richard C. Cornell to count 2.

DISPOSITION: 3–14–55, Cornell fined $250; 6–24–55, partnership fined $350 and Abel and Barton each fined $50.

4631. (F. D. C. No. 37173. S. Nos. 76–391 L, 76–394 L, 76–396 L, 76–401 L, 76–405 L.)

INFORMATION FILED: 12–8–54, E. Dist. Wash., against **William E. Willis, t/a Sun Drug Store, Spokane, Wash., and Milton E. Fisher (an employee at the drugstore).**

CHARGE: Between 12–14–53 and 1–12–54, *penicillin G potassium tablets, ergoapiol capsules,* and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription, and *phenobarbital tablets* and *dextro-amphetamine*

sulfate tablets were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty—by Willis to all counts of the information and by Fisher to counts involving dispensing of the *dextro-amphetamine sulfate tablets*.

DISPOSITION: 1–24–55. Willis fined $300 and Fisher $10.

4632. (F. D. C. No. 37171. S. Nos. 10–105/6 L, 58–988 L, 65–722 L.)

INFORMATION FILED: 1–19–55, N. Dist. Ill., against **Miltburne Drug Co., a corporation, t/a Portes Drugs, Melrose Park, Ill., Fred J. Portes (secretary, director, and apprentice pharmacist for the corporation), and William R. Bair (pharmacist for the corporation).**

CHARGE: Between 6–2–53 and 7–27–53, *penicillin G potassium troches* (count 1), *secobarbital sodium capsules* (count 2), *methyltestosterone tablets* (count 3), and *apiol capsules* (count 4) were each dispensed once without a prescription.

PLEA: Guilty—by corporation to all 4 counts of the information; nolo contendere—by Fred J. Portes to counts 1 and 2 and by William R. Bair to count 3.

DISPOSITION: 3–18–55. Fine of $150 against corporation and $100 against each individual, plus costs.

4633. (F. D. C. No. 36623. S. Nos. 63–268 L, 63–270 L, 63–272 L, 63–279 L.)

INFORMATION FILED: 11–4–54, W. Dist. Mo., against **H. Foster Evans, t/a Foster Evans Drugs, Neosho, Mo., and Doyle Norman (pharmacist).**

CHARGE: Between 2–24–54 and 3–1–54, *cortisone acetate tablets* were dispensed once upon a request for a prescription refill without authorization by the prescriber, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium*, *dextro-amphetamine sulfate tablets*, and *methyltestosterone tablets* were each dispensed once without prescriptions.

PLEA: Guilty—by Evans to all counts of the information and by Norman to counts 2 and 3 involving dispensing of the *capsules containing a mixture of secobarbital sodium and amobarbital sodium* and the *dextro-amphetamine sulfate tablets*.

DISPOSITION: 5–23–55. Evans and Norman fined $4,000 and $1,000, respectively, and each placed on probation for 2 years.

4634. (F. D. C. No. 36598. S. Nos. 59–549/51 L, 59–687 L, 59–693 L.)

INFORMATION FILED: 10–11–54, N. Dist. Ga., against **Walter B. Forbes, t/a Forbes Drug Co., Griffin, Ga., and Thomas W. Gary (pharmacist).**

CHARGE: Between 9–4–53 and 9–24–53, *cortisone acetate tablets* were dispensed twice (counts 1 and 5) and *Dexedrine Sulfate tablets* were dispensed twice (counts 2 and 4) without a prescription; and *Nembutal Sodium capsules* were dispensed once (count 3) upon request for a prescription refill without authorization by the prescriber.

PLEA: Nolo contendere—by Forbes to all counts and by Gary to counts 2, 3, and 4.

DISPOSITION: 11–29–54. Forbes—$250 fine and probation for 2 years; Gary—probation for 2 years.

4635. (F. D. C. No. 35588. S. Nos. 46-022/23 L.)

INFORMATION FILED: 10-19-54, Dist. Mass., against **Sidney Joseph Leavitt (president and pharmacist of the Terrace Pharmacy Co., Inc.), Brighton, Mass.**

CHARGE: On or about 1-4-54, *Premarin tablets* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-11-55. $100 fine.

4636. (F. D. C. No. 35587. S. Nos. 45-888 L, 45-893 L, 45-913 L, 46-018 L, 46-020/23 L.)

INFORMATION FILED: 10-19-54, Dist. Mass., against **Eaton Drug Co., Inc., Waltham, Mass., and Isadore E. Derdak (president) and Sidney Joseph Leavitt (pharmacist of the corporation).**

CHARGE: Between 12-1-53 and 1-4-54, *amphetamine sulfate tablets* and *Premarin tablets* were each dispensed once without a prescription (counts 5 and 6), and *pentobarbital sodium capsules* (counts 1 and 2) and *Benzedrine Sulfate tablets* (counts 3 and 4) were each dispensed twice upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty—by corporation to all counts; by Derdak to counts 2, 4, 5, and 6; and by Leavitt to counts 1 and 3.

DISPOSITION: 4-11-55. Corporation—$500 fine; Derdak—$250 fine; Leavitt—$100 fine.

4637. (F. D. C. No. 36620. S. Nos. 46-178 L, 89-780 L.)

INFORMATION FILED: 1-26-55, Dist. R. I., against **Andrew R. Murphy, Sr., t/a Colton Pharmacy, Providence, R. I., and Sylvester L. Reilly (pharmacist).**

CHARGE: Between 3-11-54 and 3-15-54, *Premarin tablets* were dispensed once without a prescription, and *chloromycetin capsules* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by each defendant.

DISPOSITION: 4-20-55. $200 fine against each defendant.

4638. (F. D. C. No. 36619. S. Nos. 46-147/8 L.)

INFORMATION FILED: 11-23-54, Dist. R. I., against **Star Pharmacy, Inc., Providence, R. I., and Max Greenberg (president and treasurer of the corporation).**

CHARGE: Between 2-17-54 and 2-18-54, *capsules containing pentobarbital sodium* were dispensed once upon a request for a prescription refill without authorization of the prescriber, and *apiol-ergot capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1-21-55. Corporation and individual each fined $400.

4639. (F. D. C. No. 36641. S. Nos. 89-913 L, 89-915/18 L.)

INFORMATION FILED: 10-19-54, Dist. Mass., against **Lee Drug Co., Inc., Boston, Mass., and Hyman Werlin (president of the corporation) and Albert Portnoy (pharmacist).**

CHARGE: Between 4-8-54 and 4-12-54, *secobarbital sodium capsules* (counts 1 and 4) were dispensed twice, and *amphetamine sulfate tablets* (count 2), *Ergotrate Maleate tablets* (count 3), and *pentobarbital sodium capsules* (count 5) were each dispensed once, without a prescription.

PLEA: Guilty—by corporation and Werlin to all counts and by Portnoy to counts 1, 2, and 5.

DISPOSITION: 4–4–55. Corporation—$1,000 fine; Werlin and Portnoy—each fined $500, given jail sentence of 6 months, which was suspended, and placed on probation for 2 years.

4640. (F. D. C. No. 35805. S. Nos. 69–804/6 L, 69–808 L, 69–810 L, 69–812 L.)

INFORMATION FILED: 10–14–53, Dist. Utah, against **Clearfield Pharmacy, a partnership, Clearfield, Utah, and Glade R. Day and Leslie B. Otte (partners).**

CHARGE: Between 11–12–52 and 8–27–53, *secobarbital sodium capsules* were dispensed 3 times (counts 2, 3, and 6), *sulfadiazine tablets* were dispensed twice (counts 1 and 5), and a quantity of *procaine penicillin G* was dispensed once (count 4), without a prescription.

PLEA: Guilty—by partnership to all 6 counts of information; by Day to counts 1, 2, 3, 4, and 6; and by Otte to count 5.

DISPOSITION: 6–7–54. Partnership fined $6,000; Day given suspended prison sentence of 5 years and placed on probation for 5 years; Otte fined $1,000 and given suspended prison sentence of 1 year and placed on probation for 1 year.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4601 TO 4640

PRODUCTS

[1] (4614, 4617, 4623, 4624) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4614, 4617, 4623, 4624) Prosecution contested.

[1] (4614, 4617, 4623, 4624) Prosecution contested.

[1] (4614, 4617, 4623, 4624) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1956

D. D. N. J., F. D. C. 4641–4660 Issued May 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4641–4660

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) criminal proceedings which were terminated upon pleas of guilty or nolo contendere; and (3) injunction proceedings in which decrees of injunction were entered with the consent of the parties or after trial. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Similar actions with respect to products alleged to be in violation while held for sale after shipment in interstate commerce are reported in other supplements.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 9, 1956.*

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* For omission of, or unsatisfactory, ingredients statements, see No. 4656.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4641–4660

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium, and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4641. Dr. Reilly's Applicator and Dilator Assembly (a device) and Dr. Reilly's Rectal Remedy Pile-Aid (a drug). (Inj. No. 272.)

COMPLAINT FOR INJUNCTION FILED: 1–7–54, E. Dist. Wis., against Dr. Reilly's, Inc., Milwaukee, Wis., and its president, Dr. John F. Reilly; and Hunter Enterprises, Inc., Milwaukee, Wis., and its president, Robert S. Hunter, to enjoin the interstate shipment of the above-mentioned drug and device, which were misbranded.

ACCOMPANYING LABELING: Testimonial letters dated 4–15–52 and 6–30–52 signed by Evelyn Donner and Edward R. Hoffmann, a form letter addressed to "Dear Friend" and beginning with the words "I am not only sending," a leaflet entitled "Important Information Direct from Dr. Reilly," a leaflet entitled "Dr. Reilly's Medicating Applicator," a leaflet headed "This Concerns Your Health," a form letter addressed to "Dear Friend" and beginning with the words "Until now no easy, convenient, inexpensive home treatment has been available," a form letter addressed to "Dear Friend" and beginning with the words "You will find enclosed answers to questions sometimes asked," a pamphlet entitled "Comfort for all the family," and a leaflet containing "Instructions for Use."

RESULTS OF INVESTIGATION: The device consisted essentially of a small metal pump, plastic tubing, a plastic applicator, and rectal dilators, and was designed to be attached to a bottle of the drug and to inject the drug into the rectum.

The drug consisted of a solution of camphor-phenol in mineral oil, together with a small amount of a certified coal-tar color. The drug was packaged in 8-ounce bottles suitable for attachment to the device.

CHARGE: The complaint alleged that the defendants had been and still were engaged in the business of distributing, selling, and introducing into interstate commerce the above-mentioned drug and device, which were misbranded as follows:

502 (a)—the labeling contained false and misleading representations that the articles, when used in combination, constituted an adequate and effective remedy for piles, hemorrhoids, rectal irritations, inflamed tissue,

spastic rectum, rectal fistula, rectal fissure, rectal bleeding, lower colon troubles, swollen rectal protrusions, and rectal soreness; that the articles, when used in combination, would restore normal elimination desire (regularity) and normal conditions, would re-establish rectal health, and would reduce the possibility of rectal cancer; and that the article of device was safe;

502 (f) (1)—the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended;

502 (j)—the device was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in an accompanying circular containing "Instructions for Use."

DISPOSITION: On 1–7–54, a temporary restraining order was entered against the defendants enjoining them against the acts complained of, and on 1–22–54, a preliminary injunction was entered. Thereafter, on 9–3–54, with the consent of the defendants, a decree of permanent injunction was entered enjoining the defendants against introducing into interstate commerce the device and drug involved, or any similar article of device and drug, which were misbranded as alleged in the complaint.

In addition, the decree stated that nothing in the injunction should prevent the defendants from introducing into interstate commerce the ointment designated as "Dr. Reilly's Rectal Remedy and Pile-Aid," under suitable labeling, for use for the temporary relief of itching and irritation associated with hemorrhoids, provided that a new name is adopted for such ointment which does not create the false and misleading impression that the ointment is of value in the treatment or cure of hemorrhoids, and provided further that no labeling statements, collateral literature, or advertising material is used which represents or suggests that the ointment is of value in the treatment or cure of hemorrhoids.

The decree stated also that the defendants could ship the device in interstate commerce to licensed physicians, hospitals, and clinics for professional use and to persons lawfully engaged in the storage or wholesale or retail distribution of medical devices for sale on the prescription of a physician, provided the label on the device stated the method of its application or use and bore the statement "Caution: Federal law restricts this device to sale by or on the order of a physician," and that there was made readily available to physicians licensed by law to use or order the use of the device brochures bearing information concerning the use of the device.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4642. Tryptacin tablets (47 seizure actions). (F. D. C. Nos. 35667, 35669, 35670, 35679, 35682/6, 35690, 35693, 35695, 35703, 35709/12, 35715, 35721, 35725, 35726, 35728, 35729, 36022/5, 36030/3, 36035/8, 36041/3, 36045/53, 36055, 36056, 36067, 36068, 36073, 36091/3. S. Nos. 14–743 L, 17–595 L, 19–848 L, 20–097/9 L, 20–104 L, 20–110 L, 35–520/1 L, 35–527/8 L, 39–554 L, 39–562 L, 42–630 L, 42–891/3 L, 43–163 L, 43–165/6 L, 43–169/70 L, 43–313/4 L, 47–921 L, 48–106/7 L, 58–253/5 L, 58–257 L, 58–260/2 L, 59–184/5 L, 59–392/6 L, 64–364 L, 65–375/6 L, 70–052 L, 72–361 L, 73–888/90 L, 75–976 L, 83–473/4 L, 83–477 L, 83–481 L, 83–855 L.)

*See also No. 4641.

QUANTITY: 12,028 100-tablet btls. at Atlanta, Ga.; Minneapolis and St. Paul, Minn.; Los Angeles, Oakland, San Francisco, Sacramento, and Vernon, Calif.; Chicago, Ill.; Philadelphia, Pa.; Tampa, Fla.; Charleston, W. Va.; New Orleans, La.; Denver, Colo.; Burlington, Des Moines, Cedar Rapids, Ottumwa, and Waterloo, Iowa; Everett and Seattle, Wash.; and Houston, Tex.

SHIPPED: Between 1–13–53 and 10–9–53, from Cleveland, Ohio, by Rhodes Pharmacal Co., Inc.

LABEL IN PART: (Btl.) "Tryptacin Rhodes * * * Tablets."

RESULTS OF INVESTIGATION: Advertisements concerning the use of the article in the treatment of stomach ulcers appeared in various newspapers circulated in the areas where the product was located, but the labeling of the article bore no reference to stomach ulcers.

LIBELED: Between 9–24–53 and 11–10–53, N. Dist. Ga., Dist. Minn., N. Dist. Calif., S. Dist. Calif., N. Dist. Ill., E. Dist. Pa., S. Dist. Fla., S. Dist. W. Va., E. Dist. La., Dist. Colo., N. Dist. Iowa, S. Dist. Iowa, W. Dist. Wash., and S. Dist. Tex.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to state all the conditions or diseases for which the article was intended to be taken, and its labeling failed also to bear adequate directions for use in the treatment of such conditions and diseases.

DISPOSITION: Between 11–6–53 and 8–16–54. 4 seizure actions: Default—destruction. 43 seizure actions: Consent—Claimed by Rhodes Pharmacal Co., Inc., and relabeled.

4643. C-Tone. (F. D. C. No. 36104. S. No. 45–595 L.)

QUANTITY: 27 cases, 12 8-oz. btls. each, at Cambridge, Mass.

SHIPPED: 10–9–53, from New York, N. Y., by Balanced Foods, Inc.

LABEL IN PART: (Btl.) "C-Tone The *Natural* Vitamin C Tonic."

RESULTS OF INVESTIGATION: Prior to the receipt of this shipment, the consignee had distributed to prospective customers a number of circulars entitled "Which of These Dread Killers Threaten Your Advancing Years?" These circulars were identical in text (except for the imprint of consignee) to other circulars concerning this product distributed to various dealers by the shipper of the article.

LIBELED: 11–3–53, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use in the treatment of high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, dizzy spells, and for providing energy and improving digestion, which were the conditions and purposes for which the article was intended.

DISPOSITION: 2–21–55. Default—destruction.

4644. Anterior pituitary whole ovarian solution. (F. D. C. No. 37035. S. No. 78–918 L.)

QUANTITY: 14 vials at Dayton, Ohio.

SHIPPED: 1–15–54 and 6–21–54, from Los Angeles, Calif., by American Bio-Chemical Corp.

LABEL IN PART: (Vial) "30 cc Sterile Solution Each cc contains Anterior Pituitary. . . . 25 gr. Whole Ovarian. . . . 55 gr. Chlorobutanol 0.5% Note: There is no scientific evidence available that this product has therapeutic or physiologic activity. For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription."

LIBELED: 8–6–54, S. Dist. Ohio.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 9–15–54. Default—destruction.

4645. Aqueous extract of anterior pituitary. (F. D. C. No. 37297. S. No. 83–980 L.)

QUANTITY: 26 vials at Kansas City, Mo.

SHIPPED: Between 6–1–52 and 8–13–53, from Kansas City, Mo., by Ashe Lockhart, Inc., to Minneapolis, Minn., and from there reshipped to the consignee's Kansas City office.

LABEL IN PART: (Vial) "10 c. c. Aqueous Extract of Anterior Pituitary Each c. c. contains water soluble extractives from 18½ grains fresh tissue. Contains .5% Chlorobutanol (Chloroform Derivative)."

LIBELED: On or about 10–14–54, W. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 12–31–54. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4646. Phenobarbital tablets. (F. D. C. No. 37344. S. No. 77–275 L.)

QUANTITY: 1,100 100-tablet btls. and 1 10,000-tablet tin at Skillman, N. J.

SHIPPED: 10–19–53, from Brooklyn, N. Y., by Robin Pharmacal Corp.

RESULTS OF INVESTIGATION: The tablets had been shipped in bulk; and, upon receipt by the consignee, a number of the tablets were repackaged into bottles.

LIBELED: 11–10–54, Dist. N. J.

CHARGE: 501 (b)—the strength and quality of the article when shipped differed from the standard for phenobarbital tablets set forth in the United States Pharmacopeia since the article failed to meet the test for permissible variations in the weight of individual tablets and some tablets contained more and some tablets contained less than the declared amount of phenobarbital.

DISPOSITION: 12–10–54. Default—destruction.

4647. Triple hormone suspension. (F. D. C. No. 37464. S. No. 63–593 L.)

QUANTITY: 80 vials at Memphis, Tenn.

SHIPPED: 7–19–54, from Chicago, Ill., by Maizel Laboratories.

LABEL IN PART: "10 cc. Vial Intramuscular * * * Triple Hormone Suspension Each cc. Contains: Estradiol 1.2 Mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 77 percent of the labeled amount of estradiol.

LIBELED: 12–8–54, W. Dist. Tenn.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported or was represented to possess since it contained less than the declared amount of estradiol; and, 502 (a)—the label statement "Each cc. Contains: Estradiol 1.2 Mg." was false and misleading.

DISPOSITION: 4–4–55. Consent—claimed by Maizel Laboratories and relabeled.

4648. **Ethinyl estradiol tablets.** (F. D. C. No. 37380. S. No. 60–196 L.)

QUANTITY: 659 100-tablet btls. at Miami, Fla.

SHIPPED: 8–13–54, from Brooklyn, N. Y., by Bonded Laboratories, Inc.

LABEL IN PART: (Btl.) "Estorals A brand of Ethinyl-Estradiol."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 46 percent of the labeled amount of ethinyl estradiol.

LIBELED: 11–24–54, S. Dist. Fla.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported and was represented to possess since it contained less than the declared amount of ethinyl estradiol per tablet; and, 502 (a)—the label statement "Each tablet contains 0.05 mg. crystalline pure Ethinyl-Estradiol" was false and misleading.

DISPOSITION: 1–7–55. Default—destruction.

4649. **Betathionate.** (F. D. C. No. 37438. S. No. 56–281 L.)

QUANTITY: 28 cartoned vials at Columbus, Ohio.

SHIPPED: 8–23–54, from Philadelphia, Pa., by Addison Laboratories.

LABEL IN PART: (Vial) "30 cc. Multiple Dose Vial Betathionate."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 11 times more than the declared amount of niacinamide and less than 53 percent of the declared amount of vitamin B_1 (thiamine Hcl.).

LIBELED: 11–22–54, S. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported or was represented to possess, namely, 1 mg. of niacinamide and 15 mg. of vitamin B_1 per cubic centimeter; and, 502 (a)—the label statement "Each cc. Contains: * * * Niacinamide 1 Mg. * * * Thiamine Hcl. 15 Mg." was false and misleading.

DISPOSITION: 1–11–55. Default—destruction.

4650. **Estivin.** (F. D. C. No. 37397. S. No. 18–480 L.)

QUANTITY: 10 cartons, 6 cartoned btls. each, at Los Angeles, Calif.

SHIPPED: 1–22–54, from New York, N. Y., by Schieffelin & Co.

LABEL IN PART: (Cartoned btls.) "0.25 Fl. Oz. List No. 3684 Estivin Dropak Contains A Processed Infusion of Rosa Gallica L (Rose Petals) For The Eyes."

LIBELED: 11–8–54, S. Dist. Calif.

CHARGE: 501 (c)—the purity and quality of the article when shipped fell below that which it purported and was represented to possess since the article was represented as possessing such purity and quality as would render it suitable for use in the eyes, whereas it was heavily contaminated with living micro-organisms so that it was not suitable for use in the eyes.

DISPOSITION: 12–2–54. Default—destruction.

4651. Ear wax drops. (F. D. C. No. 37556. S. No. 5–508 M.)

QUANTITY: 8 display cartons, 12 cartoned btls. each, at Highland Park, Mich.

SHIPPED: 9–14–54 and 10–25–54, from Cincinnati, Ohio, by Grandpa Soap Co.

LABEL IN PART: (Carton) "Dent's Ear Wax Drops Contains Per Fluid Ounce: 10 Grs. Chloral Hydrate % In Product 1.75% * * * 8 Mins. Fluid Extract Hyoscyamus, Containing Total Alkaloids of Hyoscyamus 0.003 Grain. Alcohol 1.0% Also Contains Carbolic Acid and Glycerin"; (btl.) "1 Fluid Dram Dent's Ear Wax Drops Containing: Glycerin, Chloral Hydrate 1.75%, total Alkaloid of Hyoscyamus 0.0007%, Carbolic Acid * * * C. S. Dent & Co. Cincinnati, Ohio."

RESULTS OF INVESTIGATION: Examination showed that the article was a yellow viscous liquid containing 21.4 grains per fluid ounce of chloral hydrate, 1.5 percent by volume of phenol, and glycerin.

LIBELED: 1–3–55, E. Dist. Mich.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it was represented to possess since it contained more than the labeled amount of chloral hydrate; and, 502 (a)—the labeling contained false and misleading representations that the article was an adequate and effective treatment for earache, and the labeling in regard to the chloral hydrate content of the article also was false and misleading.

DISPOSITION: 5–3–55. Default—destruction.

4652. Adhesive bandages and adhesive strips. (F. D. C. No. 35806. S. Nos. 54–269 L, 55–875 L, 59–244 L, 59–246 L, 59–467 L.)

INDICTMENT RETURNED: 9–8–54, Dist. Mass., against Albert H. Tessier, t/a Handy Pad Supply Co., Worcester, Mass.

SHIPPED: Between 12–19–52 and 8–11–53, from Massachusetts to Michigan, North Carolina, and New York.

LABEL IN PART: (Box) "100 Ideal Adhesive Strips * * * Sterilized Plain Sulfathiazole Gauze Pad [or "Plain Borated Gauze Pad"] Distributed by Southern First Aid Supply Co. Lexington, N. C.," "100 Redi-Dressings * * * Plain Borated Gauze Pad Sterilized Distributed by Jeffrey-Fell Company Buffalo 8, N. Y.," or "100 Dandy Bandages * * * Plain Borated Gauze Pad Sterilized Distributed by Ferrill and Schank First Aid Co. Detroit 8, Mich."

CHARGE: 501 (b)—the quality and purity of the articles when shipped fell below the standard for adhesive absorbent bandage set forth in the United States Pharmacopeia, an official compendium, in that they were not sterile but were contaminated with viable micro-organisms; and, 502 (a)—the label statement "Sterilized" was false and misleading.

PLEA: Guilty.

DISPOSITION: 3–7–55. $2,500 fine.

4653. Rubber prophylactics. (F. D. C. No. 36448. S. No. 89–003 L.)

QUANTITY: 21 gross at New York, N. Y.

SHIPPED: 11–11–53, from Philadelphia, Pa., by Zenith Drug Sales.

LABEL IN PART: "Zenith Lubri-Pak."

RESULTS OF INVESTIGATION: An examination of 144 units showed that 6 (4.2 percent) were defective in that they contained holes.

LIBELED: 3-18-54, S. Dist. N. Y.

CHARGE: 501 (c)—the quality of the article when shipped fell below that which it purported and was represented to possess; and, 502 (a)—the label statements "Prophylactic" and "For the prevention of disease" were false and misleading as applied to an article containing holes.

DISPOSITION: Irving L. Schechter, New Haven, Conn., appeared as claimant, after which the case came on for hearing before the court on the Government's motion for a final decree. After hearing the arguments of the Government counsel in support of the motion and of the claimant in opposition thereto, the court, on 1-28-55, entered a decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4654. Drugs (a brownish black liquid and a pink liquid) for use in the treatment of cancer. (Inj. No. 232.)

COMPLAINT FOR INJUNCTION FILED: November 16, 1950, Northern District of Texas, against Hoxsey Cancer Clinic, a partnership, Dallas, Tex., and Harry M. Hoxsey, to enjoin the interstate shipment of the above-mentioned drugs misbranded as hereinafter described.

CHARGE: The material allegations of the complaint are stated in the decision of the court of December 21, 1950, set forth below.

DISPOSITION: The defendants filed an answer denying the material allegations of the complaint; and, on December 14, 1950, the case came on for trial before the court without a jury. The trial was concluded on December 20, 1950; and, on the following day, the court handed down its decision, together with the following findings of fact and conclusions of law:

ATWELL, *District Judge:* "On November 15th, 1950, this complaint was filed, charging that the proceeding is brought under Sec. 302 (a) of the Food and Drug Act, 21 U. S. C. 332 (a).

"That the respondents have been and are now introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, at Dallas, Tex., in violation of Sec. 301 (a) of the Act, and 21 U. S. C. 331 (a) consignments of articles of drug within the meaning of Sec. 201 (g) of said Act, which are misbranded within the meaning of Sec. 302 of the Act.

"That the respondents promote the sale of, distribute and deliver such articles of drug from their clinic at Dallas, Texas, to physicians, and, practitioners in other portions in various parts of the United States. That such articles consist of liquids, intended for use in the mitigation, treatment and cure of cancer in man. One of such liquids is brownish-black in color, and the other, pink. Such liquids are dispatched in interstate commerce in sixteen-ounce bottles and bear the label on which appears essentially the following, to-wit:

> H. C. C. 4507 Gaston Ave., Dallas Texas, _____ No. _____ Dr. _____ One teaspoonful after meals and at bedtime. Keep cool.

That in some instances, a number appears following, 'No.' In some instances the name of J. B. Durkee appears following, 'Dr.' That the respondents in the distribution and delivery of such drugs to physicians and practitioners, dispatch such brownish-black and pink liquids in concentrated form also in sixteen-ounce bottles. The brownish-black concentrate bears a label on which appears,

> From: Hoxsey Cancer Clinic 4507 Gaston Av., Dallas, Texas. To: Regular concentrate add enough water to make one gallon. Shake well.

*See also Nos. 4641, 4647-4649, 4651-4653.

The pink concentrate bears a label on which appears,

> From: Hoxsey Cancer Clinic 4507 Gaston Ave., Dallas, Texas. To: Lactate Concentrate Add enough Lactate to make one gallon Shake well.

"That consignments of said drugs which are distributed and dispatched to physicians, practitioners, and other persons by the respondents are misbranded within the meaning of Sec. 502 (a) of the Act (21 U. S. C. 352 (a)) in that their labeling, namely, the booklet entitled, 'Hoxsey Cancer Clinic Specializing in Cancer,' accompanying said drugs, contains general and specific statements which represent and suggest that said drugs are efficacious in the treatment, mitigation and cure of cancer in man, which statements are false and misleading since said drugs are not efficacious in the treatment, mitigation and cure of cancer in man.

"That complainant is informed and believes that unless restrained by the court the respondents will continue to introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce the said drugs misbranded in the manner aforesaid.

"Complainant then prays for a perpetual injunction from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, the said drugs or any similar article of drug which is misbranded within the meaning of the Act.

"On December 5th, 1950, the respondents denied the allegations and, in that connection, said that respondents do specialize in the treatment of cancer which is done under the direction of duly licensed doctors; that they do not sell medicine, offer none for sale, and do not sell nor distribute medicine to the public.

"That the allegations that they promote the sale, or, distribution, or, deliver drugs to physicians and practitioners in other parts of the United States, they deny.

"They plead that any medicine shipped by them is that medicine which has been prescribed by a doctor and sent to a patient who is under treatment; that no patient received medicine from the clinic until after said patient had appeared in person and after having been examined by the Medical Director of the clinic, which medical examination includes blood tests, urinalysis and x-ray studies, and after said examination a prescription is made by said doctor. That the respondents have no medicine for sale and do not offer medicine for sale, nor does it advertise or distribute medicine.

"Respondents deny that the booklet referred to by complainant is a label within the meaning of the Food and Drug Act. That the booklet nowhere mentions any particular medicine, nor is the same an advertisement of the medicine. Nor is it the booklet now sent out by the respondents, but is one formerly mailed by respondents and that the booklet which is complained of by the complainant specifically refutes what complainant has alleged.

"That in this connection, the first six pages of said booklet contain an address by Dr. Durkee made in Los Angeles, California, on October 17th, 1947, which, among other things, says:

> The Hoxsey method of treatment is designed primarily to normalize the body chemistry and control normal cell metabolism—it would be well at this point to tell you about our physical equipment and our method of approach in treating a person who has cancer. Our clinic is equipped with the best diagnostic facilities obtainable. When a patient enters our clinic every laboratory procedure is used—our treatment consists basically of two groups of medications plus the supportive treatment that may be necessary.
>
> Our treatment is designed to normalize first of all the inorganic blood chemistry—we are able to show in our laboratory the changes in the blood chemistry of the patient as he undergoes treatment.

"The booklet, on page 7, among other things, contains the following:

> The Hoxsey method of treatment is not a cure-all, nor does the clinic guarantee to cure any case, which is the practice of quacks and charlatans—Patients must come to the clinic for a complete examination and laboratory analysis.

"That the foregoing quotations are not isolated statements, but are representative of the matters and things contained throughout said booklet, to-wit: a partial description of the Hoxsey method of treatment of cancer.

"I have quoted and summarized rather fully the pleadings of each side in order to give to each side that fairness of word picture which the importance of the case justifies and demands.

"After six days of the introduction of voluminous verbal testimony from both physician and patient, for both sides, and voluminous exhibit from both sides, and, having in mind the court's duty to pass upon the burden of proof, the weight of the testimony, and the credibility of the witness, I make the following

FINDINGS OF FACT

1.

"The respondent did forward in interstate commerce to physicians in other States who had been present at the Hoxsey Clinic and studied its methods and efficacy for a considerable time, and were using such medicines and prescriptions in their similar treatment.

2.

"That accompanying such shipments were booklets containing the statements and illustrations quoted in the pleadings of both complaint and respondents.

3.

"That the respondents' treatment is not injurious. Some it cures, and some it does not cure, and, some it relieves somewhat. That respondents do not guarantee to cure.

4.

"That the statements contained in said labels so pleaded, are neither false nor misleading. That if in doubt as to the effectuality of the treatment, they take the patient on trial, and, frequently, without charge to the patient.

5.

"That the percentage of efficient and beneficial treatments by respondents is reasonably comparable to the efficiency and success of surgery and radium, and without the physical suffering and dire consequences of radium, if improperly administered, and surgery, if not successful in completely removing the entire malignant portion.

6.

"That cancer is an aggregation of outlaw cells with the propensity to migrate and grow in size and in the territory covered and the definite destruction of the body, or, a serious portion thereof.

7.

"That the respondents do have two basic medicines to which are added, if and when the examination of the patient calls for such additions, a large number of drugs and medications in a separate room at the clinic. That it also subtracts and changes the basic elements of the two medicines as indicated, in the judgment of the Medical Director of the clinic when indicated by the examination of the patient, but that no such prescription accompanies shipments made in interstate commerce to the doctors in other States who are using the Hoxsey method, nor does the same appear upon the bottles or receptables of the medicine.

8.

"That the Food and Drug inspectors seized medicines and pamphlets and booklets such as are pleaded, from the doctors in other States who have been

using the Hoxsey method, and which came interstate commerce. That such seizures were prior to the institution of this suit, since which time the respondents have made no interstate shipments of either pamphlets, or, medicines.

CONCLUSIONS OF LAW

"It is not necessary that mislabeling, or, misbranding within the meaning of the Act, shall actually be on the container, but they may accompany it, or, reach the user in some other manner. There is some authority to the contrary, but I think the case of Kordel v. United States, 335 U. S. 345, and the case of United States v. Urbuteit, 335 U. S. 355, are controlling.

"The exemptions provided for in the Act with reference to physicians' prescriptions, and the placing of the contents on the bottle, or, container, are not applicable, nor can they be of any use to the respondents here, because the respondents' method in forwarding articles and pamphlets to the physicians in other States who are using the method and treatments were not so displayed. Nor can the plea of good faith, or, the charitable inclinations of the respondents save them from the rigors of the Act. Nor can the discontinuance of the practice of shipments to physicians in other States, save the respondents from the injunctive features of the Act, even though the chancellor, speaking in equity, will not require that which is useless.

"Nevertheless, the facts disclosed by the testimony and found as above, as well as the failure of the government to successfully carry the burden and show by a preponderance of the testimony, the correctness of its charges, merits, and must have, a refusal of the injunctive relief sought, and a dismissal of the bill, and such order and decree is, accordingly, announced."

On February 15, 1951, a notice of appeal to the United States Court of Appeals for the Fifth Circuit was filed by the Government; and, on July 31, 1952, after considering the briefs and arguments of counsel, the following opinion was handed down by that court (198 F 2d 273):

RUSSELL, *Circuit Judge:* "Proceeding under the provisions of the Federal Food, Drug and Cosmetic Act,[1] and relying particularly upon its provisions defining labeling,[2] prohibiting introduction into interstate commerce of any drug that is misbranded,[3] and deeming a drug misbranded 'If its labeling is false or misleading in any particular,'[4] the United States sought in the trial Court the injunctive relief provided by the Act[5] to prevent the Hoxsey Cancer Clinic, and Harry M. Hoxsey, from introducing or delivering for introduction into interstate commerce bottles of brownish-black, and pink, colored liquids intended for use in the treatment and cure of cancer in man. It is alleged that the drugs, which are distributed and dispatched to physicians, practitioners, and other persons, by defendants are misbranded, because their labeling, specifically a booklet accompanying them, contains 'general and specific statements which represent and suggest that said drugs are efficacious in the treatment, mitigation and cure of cancer in man, which statements are false and misleading since said drugs are not efficacious in the treatment, mitigation and cure of cancer in man.' Two substantially similar booklets are involved, though it appears that one is no longer used.

"For the establishment of its claims of general false and misleading statements, the Government relies upon the import and effect of statements made in an address, captioned: 'Theory and Application of the Hoxsey Method of Treating Cancer,' by 'J. B. Durkee, D. O., Medical Director of the Hoxsey Cancer Clinic, Dallas, Texas, before the Second Annual Convention of the National Medical Society October 17, 1947, held at Royal Palms Hotel, Los Angeles, Calif.,' reprinted in the booklets, as well as other statements and representations of the booklets which represent that the Hoxsey medicines are effective in the cure, mitigation, or treatment of internal cancer.

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[1] 21 U. S. C. 301, et seq.
[2] 21 U. S. C. 321 (m).
[3] 21 U. S. C. 331 (a).
[4] 21 U. S. C. 352 (a).
[5] 21 U. S. C. 332.

"The claim of specific misrepresentations is predicated upon the contention that a division of the contents of the booklet, which includes the listing of individuals with their post office address and statement of the portion of the body on which the cancer appeared, reprint of proceedings and testimony of patients thereupon given, 'before and after' treatment photographs and comment thereon, and the invitation to write to the individuals listed 'requesting first hand testimony regarding our treatment' when read in conjunction with the statement ' "we wish only to present the facts and records of results and benefits received by those who have taken our treatment" * * * leaves the clear representation that the persons named were cured of cancer by the Hoxsey drugs.' The truth is said to be that 'any of these specific representations are downright falsehoods.'

"The defense, in the trial Court by pleading and testimony, and renewed hereby argument and brief, challenges each and all of the Government's contentions. The position of the defendants is that, as to the claim of general representations, the contents and statements of the booklets, considered as a whole, expressly deny that the medicines will cure all cases, but only that they cure some, do not cure some, and 'relieve some somewhat.' As to the specific charges of misbranding, the defendants' argument is mainly that by use of the word 'patients' in reference to the individuals listed in the booklet there is removed any idea that such persons have been cured. However, it is further contended that the testimony does show that many of the listed individuals were succesfully treated and, in some instances, cured. Underlying the entire argument is the fundamental contention that the medicines in question are efficacious in some instances in the cure and alleviation of cancer, and that they represent a 'revolutionary treatment,' which is, in many cases, successful. Running through the entire defense is the claim that the medicines and supportive treatments produce a higher percentage of more satisfactory results in the treatment of cancer than is secured by the other methods of treatment more generally employed of either X-ray, surgery, radium, or, in some instances, use of some of the by-products of atomic bomb production. These so-called orthodox methods are criticised as ineffective and in some cases positively harmful, whereas defendants contend their treatment does not have such harmful results and yet secures a higher percentage of cures.

"The issues thus arising are still present here and require for their solution determination of what representations, general or specific, the booklets may fairly and reasonably be determined to make in the circumstances to which they relate and to the persons to whom they were made, and whether, as so construed and found, the representations are false and misleading within the terms of the statute. Implicit in the latter, and actually controlling here, is whether the Government maintained either or both of its positions that the medicines in question were not efficacious in the cure of cancer in man, and that, in any event, assuming that its claim of specific representation had been established, it had proved such representation to be false.

"The trial Court made findings of fact and entered conclusions of law,[6] and, upon the ultimate ground that under the testimony as a whole the Govern-

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[6] "FINDINGS OF FACT—

1.

"The respondent did forward in interstate commerce to physicians in other states who had been present at the Hoxsey Clinic and studied its methods and efficacy for a considerable time, and were using such medicines and prescriptions in their similar treatment.

2.

"That accompanying such shipments were booklets containing the statements and illustrations quoted in the pleadings of both complainant and respondents.

3.

"That the respondents' treatment is not injurious. Some it cures, and some it does not cure, and, some it relieves somewhat. That respondents do not guarantee to cure.

4.

"That the statements contained in said labels so pleaded, are neither false nor

ment had failed to show the correctness of its charges, concluded that the injunctive relief sought should be denied.

"The Government, as appellant here, strenuously insists that the trial Court's findings and conclusions evidence misapprehension of the legal effect of the competent evidence, as well as failure to apply the controlling law. It is urged that the competent evidence in the case presents undisputed proof of the Government's specific charges of misbranding which entitled the Government to a decree in its favor; that the Court's findings were erroneously induced by consideration of, and reliance upon, incompetent testimony from laymen that they had cancer; and that they were cured; and that the controlling finding by the trial Court that the Hoxsey drugs are not falsely represented as cancer cures and that they do cure cancer are clearly erroneous, should be set aside, and the issuance of an injunction directed by this Court. Appellees relying upon the Court's finding that the treatment 'cures some, and some it does not cure, and some it relieves somewhat. That respondents do not guarantee to cure,' cite it as confirmation of the finding that the representations of the booklet are neither false nor misleading.

"Our consideration of the booklets, which concededly constitute the labeling referred to by the statute,[7] leaves us in no doubt that as concerns the nature and extent of general representation the content and statements of the booklet are intended to, and do, convey the claim that the Hoxsey medicines present a

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misleading. That if in doubt as to the effectuality of the treatment, they take the patient on trial, and frequently, without charge to the patient.

5.

"That the percentage of efficient and beneficial treatments by respondents is reasonably comparable to the efficiency and success of surgery and radium, and without the physical suffering and dire consequences of radium, if improperly administered, and surgery, if not successful in completely removing the entire malignant portion.

6.

"That cancer is an aggregation of outlaw cells with the propensity to migrate and grow in size and in the territory covered and the definite destruction of the body, or, a serious portion thereof.

7.

"That the respondents do have two basic medicines to which are added, if and when the examination of the patient calls for such additions, a large number of drugs and medications in a separate room at the clinic. That it also subtracts and changes the basic elements of the two medicines as indicated, in the judgment of the Medical Director of the clinic when indicated by the examination of the patient, but that no such prescription accompanies shipments made in interstate commerce to the doctors in other states who are using the Hoxsey method, nor does the same appear upon the bottles or receptacles of the medicine.

8.

"That the Food and Drug Inspectors seized medicines and pamphlets and booklets such as are pleaded, from the doctors in other states who have been using the Hoxsey method, and which came interstate commerce. That such seizures were prior to the institution of this suit, since which time the respondents have made no interstate shipments of either pamphlets, or, medicines.

"CONCLUSIONS OF LAW—

"It is not necessary that mislabeling, or, misbrandings within the meaning of the Act shall actually be on the container, but they may accompany it, or, reach the user in some other manner. There is some authority to the contrary, but I think the case of Kordel v. United States, 335 U. S. 345, and the case of United States v. Urbuteit, 335 U. S. 355, are controlling.

"The exemptions provided for in the Act with reference to physicians' prescriptions, and the placing of the contents on the bottle, or, container, are not applicable, nor can they be of any use to the respondents here, because the respondents' method in forwarding articles and pamphlets to the physicians in other states who were using the method and treatments were not so displayed. Nor can the plea of good faith, or, the charitable inclinations of the respondents save them from the rigors of the Act. Nor can the discontinuance of the practice of shipments to physicians in other states, save the respondents from the injunctive features of the Act, even though the Chancellor, speaking in equity, will not require that which is useless.

"Nevertheless, the facts disclosed by the testimony and found as above, as well as the failure of the government to successfully carry the burden and show a preponderance of the testimony, the correctness of its charges, merits, and must have, a refusal of the injunctive relief sought, and a dismissal of the bill, and such order and decree is, accordingly, announced."

[7] Kordel v. United States, 335 U. S. 345; United States v. Urbuteit, 335 U. S. 355.

successful cure for cancer in only some cases, but the recitation of their virtues is so emphasized and reiterated as to induce in the mind of one thinking he suffered from cancer a belief that he had an excellent chance to be one of those cases in which the medicine would be successful. The language and entire contents are so hedged about with denials that the treatment is a 'cure-all,' or effective in all cases, that its true import is only that the medicines are effective in a substantial number of cases. For the purpose of this decision, and in determining the truth of such representations, we will accept the more restricted position, to which the Government is driven, that the precise extent of successful cures is immaterial since, it is contended, that the representation that *any cure* can be effected by use of the medicines is false and misleading. We think the claim of specific representation that the parties listed and given as references for testimonials is sustained to the extent claimed by the Government. It is difficult to imagine that one thinking himself inflicted with the dire disease of cancer and reading and considering the references to these listed patients, and the testimony there set forth, and which is prefaced as this is [8] and reiterated by conclusion,[9] would reach any other conclusion than that the persons listed were cured of cancer by the Hoxsey drugs. It is common knowledge that such is the representation of 'testimonial letters as is the usual custom.' It is clear that the general representation is that at least the Hoxsey medicines will cure some cancer, and the specific representation is that it has cured the persons listed as patients, and who have testified as to cure, and to whom it is suggested letters be addressed to obtain testimonials to the efficacy of such medicines. The question of whether these representations are false and misleading remains.

"In approaching this question we are guided by some well recognized beliefs and experience so universally entertained and accepted by the practically unanimous aggregate of medical science as that contradiction thereof does not raise a substantial issue of fact. Thus, with practical unanimity, those informed and in position to know are of the firm belief that there is only one reliable and accurate means of determining whether what is thought to be cancer is, in truth and fact, actually cancer. This requires a biopsy, a microscopic examination of a piece of tissue removed from the infected and question diseased region. From this it follows that the opinion of a layman as to whether he has, or had, cancer, or a like opinion as to whether he has been cured and no longer bears the disease, if, in fact, it ever actually existed, is entitled to little, if any, weight. It is further true that despite the vast and continuous research which has been conducted into the cause of, and possible cure for, cancer the aggregate of medical experience and qualified experts recognize in the treatment of internal cancer only the methods of surgery, X-ray, radium and some of the radio-active by-products of atomic bomb production. This is so even though the ghastly truth is that these methods frequently fail and are, in many cases, themselves unsatisfactory. But it is true, nevertheless, that with present enlightenment they are our sole defense against the scourge of cancer. We think this statement evidences no acceptation of any particular school or segment of qualified expert medical opinion and belief, though it is not to say that persons activated by self-interest or ignorance may be found to express a contrary opinion. It is to say, however, that upon such subjects a Court should not be so blind and deaf as to fail to see, hear and understand the import and effect of such matters of general public knowledge and acceptance, especially where they are established by the overwhelming weight of disinterested testimony as appears in the record now before us.

"Two liquid medicines which are shown to have been distributed by the defendants in interstate commerce for use in treatment of cancer are involved

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[8] "We are not going to use printed space for testimonial letters as is the usual custom, however, you will find a list of patients following, with cases no doubt paralleling your own. We are giving you their names and addresses. If you will write, enclosing a self-addressed, stamped envelope we feel you will receive a testimonial first-hand."

[9] "Space does not permit us to give a complete list of all our patients, therefore, we have selected the above cases for the reason that they represent a cross section of the various types of patients treated at this institution.

"You will no doubt find in this list a condition similar to that with which you or some member of the family are afflicted. We would suggest that you correspond with some of these patients, enclosing a self-addressed envelope, requesting first-hand testimony regarding our treatment."

in this action.[10] One is a black, or brownish-black mixture; the other a pink medicine. Their respective formulae are neither secret nor contested. The analysis of samples of the drugs showed that the proportion of ingredients of the black medicine varied, but contained potassium iodide and extracts, (omitting the scientific names), from prickly ash bark, buckthorn, red clover blossom, alfalfa, and cascara sagrada. The pink medicine contained potassium iodide and lactate of pepsin. These drugs are shipped in 16-ounce bottles, to patients in diluted form, and to osteopaths in concentrated form with direction to add enough water (in case of the black), or elixir of pepsin (in case of the pink), to make a gallon. Illustrative analyses of the dilution are: water, 62 percent, potassium iodide, 26.4 percent, plant extractives, 7.9 percent, mineral matter other than potassium iodide, 6/10ths of 1 percent, and licorice flavoring; another, water, 53.2 percent, alcohol, 5.1 percent, sugars, 12/6 percent, potassium iodide, 29½ percent, and the presence of pepsin; another, water, 94½ percent, potassium iodide, 4½ percent, plant extractives, 9/10ths of 1 percent, and the presence of a licorice like flavoring; another, water, 76 percent, alcohol, 7.2 percent, sugars, 15 percent, potassium iodide, 1.3 percent and the presence of pepsin, and this was a 'slightly acid preparation.' The source of supply is the Hoxsey Cancer Clinic in Dallas, Texas. The defendant, Harry M. Hoxsey, is not a doctor, but a layman. It is his claim that the Hoxsey cancer drugs were originated by his grandfather about 1840 in Kentucky; were later used by his son, the defendant's father, and after the defendant's father's death in 1919 the present Mr. Hoxsey carried on the treatment and preparation of the drugs at the clinic, which was in charge of a doctor. The present director is Dr. J. B. Durkee, a doctor of osteopathy. The clinic operates through osteopaths and the drugs may be obtained from the clinic in Dallas, or from osteopaths in other states who have obtained the medicines by shipments from the clinic. The clinic does not maintain hospital facilities and patients who go there for treatment take the medicines away with them for self-administration. Supplies are replenished by shipments of the medicines to them.

"Upon the trial the Government, after establishing the interstate shipments of drugs and booklets, and testimony as to the formulae and analyses of the drugs in question, introduced the testimony of highly qualified and experienced experts as to the pharmacological and pathological reaction and effect of the drugs in the Hoxsey medicines. Dr. David I. Macht, a physician specializing in pharmacological and experimental therapeutics, with impressive qualifications, who has done work on potassium iodide and emodin bearing drugs such as cascara sagrada and buckthorn, testified that potassium iodide could cause untoward reactions in most people. The amount received from the black medicine, when taken as recommended, could cause damage in some people. There is no basis for therapeutic use of the drugs found in the medicines, or any combination of them in the treatment of cancer. A pathologist, Dr. Max A. Goldzieher, likewise qualified and experienced in his specialty, had conducted extensive research in cancer and in connection with his research had studied and experimented in the use of potassium in cancer in afflicted animals and also upon a group of 27 volunteer patients, all of whom were 'very far gone, inoperatable and obviously incurable cases of cancer.' From these studies and experiments, he concluded that potassium increases the rate of growth in cancer and is not advisable in cancerous patients. It was his opinion, based upon such experiments, that the result of a patient with a malignant growth taking a daily dose as prescribed of the Hoxsey medicine would be to speed the growth of the cancer. Testimony was also presented of a controlled laboratory experiment carried out at the Jackson Memorial Laboratories, Bar Harbor, Maine, an institution engaged in the fundamental research of the biology of cancer, to show the effects of both types of Hoxsey medicine in treating cancerous mice. The physicians and scientists participating in the test possessed superior qualifications and extensive experience in such matters. It is shown that the manner and method of such experiments was in accord-

[10] Throughout the booklets referred to, and in the testimony, there are references to external, or skin cancers also. The defendants, in addition to the liquid medicines for the treatment of internal cancer, also have an escharotic treatment for external, or skin, cancer. This consists of a corrosive or caustic substance the basic ingredient of which is arsenic. The Government makes no contention as to this medicine, or with reference to external cancer, and consequently this medicine and the question of its use and efficacy in the treatment and cure of external cancers, and, in fact, the entire subject of external cancers is not here involved.

ance with the best known and accepted practice and was applicable to the treatment of cancer in humans to the extent that 'those agents which have been shown to produce beneficial effects against cancer in man, in general have been—they produce definite beneficial effects in some cancer on experimental animals.' The Hoxsey medication had no beneficial therapeutic effect on the cancer of the afflicted mice. It was testified by Dr. R. L. Clark, an expert of superior qualification and experience, that the recognized and only accurate method of diagnosing cancer is by a biopsy examination of the tissue, made by someone who has made a special study of the process. He stated that he knew of no medicine taken orally that would cure cancer, and he considers that there are two different methods of curing cancer known today, 'one of them is by removing the tumor by surgery, generally, and the other one is by using radiation therapy, which constitutes X-ray, radium, and more recently some of the products, by-products, of the atomic bomb production.' This witness was one of five directors and medical consultants at the Atomic Energy Plant at Oak Ridge, Tennessee.

"Against this background the Government developed its case by presenting testimony in the form of case histories of sixteen persons who had taken the Hoxsey medicine for treatment of internal cancer. Nine of these persons are among those listed in that part of the booklet which we have held to constitute specific representations of cure. We shall not undertake to lengthily detail the voluminous evidence. It followed the general pattern of showing physical examination, the making of the biopsy and pathological examination of the tissue, and dependent upon the facts in the particular case, that, where actual malignancy was present it was neither retarded nor cured by the use of the Hoxsey medicines; or there was in fact no malignancy; and that certain of the persons who had cancer were operated on for cancer, or died, while taking the Hoxsey treatment; that one patient with cancer declined surgery, used the Hoxsey medicine, but died of cancer; and one regressed while taking the medicine but improved with subsequent X-ray therapy. Each of these critical circumstances was shown by the testimony of examinations, diagnoses and result by medical doctors, pathologists, and scientific examination, all had and done in accordance with the generally accepted and approved methods and means of ascertaining and determining the facts in such instances. If such testimony be accepted as credible, it clearly establishes the Government's contention that the Hoxsey drugs in question are not efficacious in the treatment, mitigation and cure of cancer in man, contrary to the general representation of the booklet, and that the specific representation as to nine of those persons listed by name in the booklet are not true in that such persons were not cured of cancer by the use of such drugs.

"The defendants countered the case of the Government with testimony as to twenty-two cases of claimed cancer cure, as well as the testimony of three osteopaths, Dr. Durkee, the director of the clinic, Dr. Macauley, a general practitioner of Jefferson City, Missouri, and Dr. Downs of Denver, Colorado. Mr. Hoxsey did not testify. Eleven of the twenty-two cases concerned alleged cancer of the skin and the result of the use of the Hoxsey powder and salve. Some of these also took the internal medicine, though it is not shown that this had any effect upon the alleged cancer and the testimony is to the effect that the powders and salves were escharotics which destroyed the cancer tissue, as well as the normal tissue. In any event, the Government made no charge with reference to the powder or salve or to external or skin cancer, and contends here, correctly we think, that these eleven cases were irrelevant to the question in issue, which dealt solely with the efficacy of the black and pink drugs taken orally for the cure of internal cancer. In three of the remaining eleven cases of alleged cancer cure the only evidence that the patient actually had cancer when he went to the clinic was the testimony of the witness. Each of these was a patient at the clinic prior to the beginning of Dr. Durkee's employment there in 1946. Over the objection of the Government, they were permitted to testify that they had cancer. In the cases of four of the eight remaining alleged cancer cures the Government introduced medical testimony of doctors who had treated and operated on the patients to show that the cancerous condition had been successfully treated before the patient went to the Hoxsey Clinic. In three of these cases the absence of malignancy was shown by pathological examination. After apparent cure, these patients went to the Hoxsey Clinic and took the liquid medicine. In one of

the cases within fifteen days after the negative result of the biopsy examination had been ascertained, Dr. Durkee, without a biopsy, stated he found cancer. In the four remaining cases the patients were likewise permitted to testify that they had cancer, or had been told that they had cancer, but there is no evidence of biopsy, and any proof of the nature of the disease these patients suffered is dependent upon the diagnosis and testimony of Dr. Durkee. Under these circumstances, the Government contends that in no instance is there reliable scientifically acceptable evidence that the patient had a cancer when the Hoxsey medication was instituted. Dr. Macauley had practiced his profession since 1941 and had spent approximately a year at the Hoxsey Clinic. He admitted that he is not a cancer expert. He conceded that the only proper method of diagnosing a cancer is to make a biopsy and pathological examination of the tissue. Dr. Downs testified to the same effect. Dr. Durkee testified that he did not 'need a biopsy to make a diagnosis of cancer.' Substantially his entire experience and practice with cancer has been at the Hoxsey Clinic where during the past five or six years he has personally examined or treated five or six thousand patients. He personally examines all of the patients, seeing thirty-five to fifty a day, and spending between five and ten minutes with each on the average, though with some longer than others. Of this number, he estimates he has taken between three and four hundred biopsies. Not many were made of patients by other people at his request.

"The above restricted summaries are not stated in an attempt to review in detail a voluminous record, but to show the general nature of the case put forward by the plaintiff and the defendant and to point up the difference in the type of proof presented by the Government to establish the allegations of the complaint, and the type of proof relied upon by the defendant to cast doubt upon the Government's case as thus presented.

"Based upon the claim of supremacy of scientific testimony and pathological examination over the opinions of lay witnesses that they had cancer and were cured, or their hearsay testimony of what doctors had told them of their condition, and likewise over the testimony of Dr. Durkee, who, it is contended, was not only a vitally interested witness, but also without sufficient qualifications as an expert, the Government contends that as to the nine instances of specific misrepresentations its evidence is actually undisputed and requires a decree in its favor. It is also contended that it was prejudicial error for the trial Court to permit laymen to testify that they had, or were cured of, cancer, or as to what a physician had told them as to their condition. The third major contention of the Government is that the trial Court's findings that the Hoxsey drugs are not falsely represented as cancer cures and that they do cure cancer are clearly erroneous.

"We have already stated the effect we think proper to give to the general and specific representations set forth in the booklets, the labeling of the drugs. Our consideration of the record and the nature of the issues involved has led to the firm conclusion that the trial Court's findings of fact that the representations in the labeling were neither false nor misleading, and that the brownish-black and pink colored medicines were efficacious in the cure of cancer in man are clearly erroneous. Thus, even if it be assumed, *arguendo*, that there is *some* measure of conflict in the evidence relating to the falsity of the specific representations referred to above, still, it is clear that a finding that such representations are true is not supported by substantial evidence. It is equally clear that without regard to any general rule of admissibility of the testimony of laymen as to the existence of disease or physical injury or as to the curative effect of drugs,[11] when the subject of investigation is the existence of cancer, the personal testimony of the lay sufferer is entitled to no weight, since the overwhelming preponderance of qualified opinion recognizes that not even the experts can assuredly diagnose this condition without the aid of biopsy and pathological examination. Hearsay testimony of what such a person has been told by a physician is entitled to no greater weight. Except for such testmony and the testimony of the three osteopaths, two of whom did not claim to be experts on the diagnosis

[11] Cf. United States v. 141 Bottles of Drug Products, S. D. Texas not reported; affirmed in Hall v. United States, 5 Cir., 267 Fed. 795; Federal Trade Commission v. Kay, 35 F. 2d, 160, 162.

and treatment of cancer, and the third of whom is a definitely interested witness who testified as to ability to diagnose contrary to all accepted scientific knowledge, the testimony on behalf of the Government in the full and complete establishment of its case of misbranding is not substantially disputed. We think this so-denominated conflicting evidence is wholly insufficient to cast such doubt upon the testimony adduced in behalf of the Government as to authorize the trial Court to find that the Government had failed to carry the burden of establishing the truth of the allegations of its complaint. To the contrary, we think that the evidence in this case, considered as a whole, should, and must, induce a conviction that the finding of the trial Court that the representations were neither false nor misleading is so 'against the great preponderance of the credible testimony that it does not reflect or represent the truth and right of the case.' [12] On the entire evidence we are 'left with the definite and firm conviction that a mistake has been committed.' *United States* v. *Gypsum Co.*, 333 U. S. 364, 395. We recognize, as we must, that the cause, effect and cure of cancer are so obscure and indefinite that there obtains in the entire subject an area of the unknown. It is nevertheless the duty of a Court in making determination of questions of such great public moment as those which now confront us to give weighty consideration to the experience of the past and the accepted views and findings of science as held and confirmed by such experience and as likewise shown by the weight of the testimony to be applicable to the specific facts of this case. In this, as in other similar matters, that not all, or even little, is known about the subject does not require us to disregard that which is known and established. We do not have for consideration the merits even of any claimed newly discovered, or secret, drug or cure. The case involves the efficacy of only well known drugs. As a cure for cancer these have been weighed and found wanting.

"It was not necessary for the Government to prove that each and every representation in the booklet was false or misleading. The statute seeks to prevent labeling which is false or misleading in any particular. Proof that such representation in the case of at least nine of the persons represented as cured was false establishes the falsity of such representation in a most significant particular. Furthermore, as we have held, the overwhelming weight of the credible evidence requires a conclusion that the representation that the Hoxsey liquid medicines are efficacious in the cure of cancer is likewise false and misleading. The evidence as a whole does not support the finding of the trial Court that 'some it cures, and some it does not cure, and some it relieves somewhat.'

"We do not attempt to set ourselves up as arbiters of what method of treatment the Hoxsey Clinic shall employ. We are not authorized by law to do so. It is our duty to adjudge the merits of the case in the light of the provisions and intent of the Federal Food, Drug and Cosmetic Act, *supra*, which close the channels of interstate commerce against drugs which are misbranded. There is no question in this case but that the drugs, with the accompanying labels, were distributed by the defendants in interstate commerce to patients, as well as to Dr. Downs. It is stipulated that one such shipment was made to a patient only a few days before the beginning of the trial. We find these shipments and the accompanying labels to come within the prohibition of the statute and the finding of the trial Court to the contrary to be clearly erroneous.

"The facts of the case require the issuance of an injunction, and the Court's failure to do so evidences an abuse of discretion. The judgment of the trial Court is reversed, and the cause remanded with direction that the trial Court order an injunction to issue as prayed.

"REVERSED, AND REMANDED, with direction."

On December 8, 1952, the defendants filed with the United States Supreme Court a petition for a writ of certiorari; and, on February 2, 1953, such petition was denied.

The United States District Court for the Northern District of Texas entered a decree on June 29, 1953, permanently enjoining the defendants from directly, or indirectly, introducing and delivering, for introduction into interstate commerce, the drugs which were the subject of the complaint, or any similar

[12] Sanders v. Leech, 158 F. 2d. 486.

drugs, and which were misbranded. The decree further provided that the misbranding under Section 502 (a), which was prohibited by the injunction, applied to such drugs, the labeling of which was false and misleading in any particular within the meaning of the Act. It also specifically prohibited the use as labeling of the drugs, the white booklet entitled "Hoxsey Cancer Clinic Specializing in Cancer" consisting of 44 pages and the blue booklet entitled "Hoxsey Cancer Clinic" consisting of 58 pages; also prohibited was the labeling of such drugs which represented, suggested, or implied that the drugs were beneficial, effective, or had value in the cure, mitigation, or treatment of any type of cancer in human beings without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations.

On August 8, 1953, the Government filed with the United States Court of Appeals for the Fifth Circuit a petition for a writ of mandamus to the United States District Court for the Northern District of Texas, based on the district court's failure to comply with the mandate of the court of appeals. On October 22, 1953, the court of appeals handed down the following opinion:

PER CURIAM: "Alleging that, though directed by the mandate of this court to 'order an injunction to issue as prayed,' the district judge had failed and refused to do so, the United States of America filed its petition, praying that a writ of mandamus issue to Judge William H. Atwell, Judge of the United States District Court for the Northern District of Texas, 'To vacate and expunge the final decree of June 29, 1953, so far as it fails to conform to the mandate of this Court, by striking from the said final decree the words reading as follows: "without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations."'

"A show cause order having issued as prayed in the petition, Judge Atwell filed his answer to the order as follows:

> COMES NOW William H. Atwell, Judge of the United States District Court for the Northern District of Texas, in answer to the order made by this Honorable Court, which order is dated February 7th, 1953, and which order is predated before the complained of injunction was signed by me. Such order was not signed until June 29, 1953.
>
> Such order in all respects corresponds to the judgment of this Honorable Court, save and except the paragraph which is now objected to by the government, reading as follows:
>
> > "Without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations."
>
> The opinion of this Honorable Court shows distinctly that it recognized that there were different opinions as to the curative value and power of the defendant's remedies.
>
> In addition to such statement by this Honorable Court in its opinion was the great volume of testimony from witnesses in person who appeared and testified that they had been cured of skin cancer by the defendant's treatment and remedies. Photographs of the afflicted persons, both men and women, were offered in evidence, and identified by the respective witnesses as photographs of themselves when they were so suffering. And as they testified in court, there were no such blemishes, or, skin disorders that could be seen.
>
> This statement is made with great respect and with the statement that the McAnnulty healing case, 187 United States, when reexamined, as shown 338 United States, does not do away with the power of the trial court to pass upon the weight and credibility of the testimony.
>
> In the oral opinion which I rendered at the conclusion of the trial of the case, I held the government had not satisfied the burden of proof resting upon it.
>
> With great respect, I am
> Yours very earnestly,
>
> (S.) W. H. Atwell,
> United States District Judge.

"Thereafter an application was made to this court by the Hoxsey Cancer Clinic and Harry M. Hoxsey for leave to intervene in the mandamus proceeding. In the alternative, if such leave was denied, its counsel sought leave to file a brief amicus curiae. Leave to intervene was denied, leave to file a brief amicus curiae was granted, and the brief was filed.

"We are of the clear opinion, for the reasons hereafter briefly stated, that the decree of the court to the extent complained of in the petition is in direct conflict with our mandate, that the answer of the district judge to the show cause order not only presents no reason why the mandate should not issue as prayed, but, on the contrary, shows that it should, and that the complained of paragraphs should be stricken and expunged from the decree.

> It is settled that if the lower court misconstrues a decree of an appellate court and does not give full effect to the mandate his action may be controlled by a writ of mandamus. Whatever was before the appellate court and disposed of by the decree is considered as finally settled and becomes the law of the case. The trial court must carry the decree into execution according to the mandate. In re Potts, Petitioner, 166 U. S. 263. [In Re N. V. Zuid-Hollandsche Scheepvaart Mattschappij of Rotterdam, 64 F (2) 915.]

"The district judge, in his letter attached as Exhibit 'C' to the petition, in which he stated that he would sign the decree presented by the United States for entry, recognized this to be the law. In that letter he stated, 'The order seems to be in accordance with the direction of the Circuit Court of Appeals and I will sign the order on June 29th, when the case is set down for final disposition.'

"Instead, however, of signing the order as presented, he added to it language which had the effect of emasculating, if not of completely nullifying, the mandate. This is made plain not only by a comparison of mandate and decree but by the respondent's answer. Conceding in it that the complained of addition to the decree, 'without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations,' does not correspond to the judgment of this court, he attempts to justify its use in his decree by challenging the correctness of the mandate. Stating, 'the opinion of this Honorable Court shows distinctly that it recognized that there were different opinions as to the curative value and power of the defendant's remedies. * * * that the McAnnulty healing case, 187 United States, when re-examined, * * * does not do away with the power of the trial court to pass upon the weight and the credibility of the testimony. * * * In the oral opinion which I rendered at the conclusion of the trial of the case, I held the government had not satisfied the burden of proof resting upon it,' he asserts in effect that he has a right to correct our mandate to conform to these views.

"Thus reasserting the correctness of his judgment, which this court had reversed, and the incorrectness of our judgment reversing it, the respondent instead of confessing error in not accepting and giving effect in his decree to the judgment of reversal, defends the reinstatement of his own judgment to the extent accomplished by the addition to the decree. This he may not do.

"In accordance, however, with the practice of this court, which proceeds on the assumption that the district judge will conform to this court's directions herein contained, without the necessity of issuing the writ prayed for, In re N. V. Zuid-Hollandsche Scheepvaart Mattschappij of Rotterdam, supra, a copy of this opinion will be certified to the district judge for his guidance, and the writ will not at this time issue."

ATWELL, *District Judge:*

DECREE OF PERMANENT INJUNCTION

"Pursuant to the Mandate of the United States Court of Appeals for the Fifth Circuit dated July 31, 1952, directing that an order for injunction issue in this case as prayed, the following Injunction is ordered to issue:

"ORDERED AND DECREED That Hoxsey Cancer Clinic, a partnership doing business at Dallas, Texas, and Harry M. Hoxsey, of Dallas, Texas, and

their agents, servants, employees, representatives, attorneys and assigns and all persons in active concert or participation with them are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce in violation of 21 U. S. C. 331 (a) the following drugs, so long as they are misbranded within the meaning of 21 U. S. C. 352 (a) as hereinafter set forth.

"The drugs referred to are:

"(1) A brown or blackish-brown mixture which contains potassium iodide, sugar, water, and extracts from one or more of the following: cascara sagrada, common buckthorn, alfalfa, red clover blossoms, and northern prickly ash;

"(2) a pink mixture which contains potassium iodide and elixir lactate of pepsin; and

"(3) any similar drugs.

"The misbranding under 21 U. S. C. 352 (a) which is prohibited by this injunction applies to said drugs, or any of them, the labeling of which is false or misleading in any particular within the meaning of said Act, and the use as labeling on said drugs, or any of them, of a white booklet entitled 'Hoxsey Cancer Clinic Specializing in Cancer,' consisting of 44 pages and a blue booklet entitled 'Hoxsey Cancer Clinic' consisting of 58 pages, which were involved in this action, are specifically prohibited; also, the labeling thereof which represents, suggests or implies that the drugs are beneficial, effective or have value in the cure, mitigation, or treatment of any type of cancer in human beings is prohibited.

"IT IS FURTHER ORDERED AND DECREED that costs are assessed against the defendants in favor of the plaintiff."

In accordance with the above opinion of October 22, 1953, the United States District Court for the Northern District of Texas entered, on October 26, 1953, a decree of permanent injunction against the defendants identical to its decree of June 29, 1953, except for the deletion of that portion which the appellate court had determined to be contrary to its mandate.

Following the appellate court's decision of October 22, 1953, in which leave was denied to the defendants to intervene in the mandamus proceedings, the defendants filed a petition for a writ of certiorari with the United States Supreme Court to review the appellate court's denial of leave to intervene. On November 30, 1953, the Supreme Court denied the petition for certiorari.

An appeal to the United States Court of Appeals for the Fifth Circuit was taken by the defendants from the district court's decree of October 26th; and, after a hearing in the matter, the appeal was dismissed by the appellate court on May 14, 1954.

On August 24, 1954, costs of $5,520.08 incurred by the Government in the injunction action were taxed against the defendants. Thereafter, a motion to retax the costs was filed by the defendants, and on September 9, 1954, the motion was overruled by the district court.

4655. Testo-Glan and Fem-Tone. (F. D. C. No. 35841. S. Nos. 40–242 L, 53–947 L.)

INFORMATION FILED: 7–16–54, E. Dist. N. Y., against Leo Shine, t/a Glanex Products and Medical Products, Floral Park, N. Y.

SHIPPED: Between 11–20–53 and 4–2–54, from New York to Arizona and Missouri.

LABEL IN PART: (Btl.) "Testo-Glan Male Formula Regular Strength Contents 60 Capsules Each capsule contains—Hormonal activity as found in wheat—Testosterone (Male Sex Hormone). . . . 0.067 mcg. Vitamin E. . . . 0.034 mgms. Survival Factor. . . . Vitamin B_1 5 mg. 500% MDR. Vitamin B_2 3.5 mg. 175% MDR. Niacinamide . . . 15 mg." and "Fem-Tone Female Formula Contents 60 Capsules Each capsule contains—Hormonal activity as

found in wheat—Estrone (Female Sex Hormone) 0.005 mcg. Vitamin E. . . . 0.034 mgms. Survival Factor . . . Vitamin B_1 5 mg. 500% MDR. Vitamin B_2 3.5 mg. 175% MDR. Niacinamide . . . 15 mg."

ACCOMPANYING LABELING: (Testo-Glan) Folder entitled "For Men Past 40 Testo-Glan The New Extra Safe Male Power Formula" and a form letter addressed to "Dear Friend" and beginning with the words "Men past 40 everywhere are praising Testo-Glan"; (Fem-Tone) a folder, one page of which was entitled "Fem-Tone Female Hormone Activity Formula."

CHARGE: *Testo-Glan.* 502 (a)—the name by which the article was designated and certain statements and graphic matter in the labeling of the article when shipped represented and suggested that the article contained physiologically active glandular substances; that the glandular constituents of the article would be of value in overcoming glandular deficiences in the human male; that the article would increase male power; that the article would be an adequate and effective treatment for male sexual weakness, mental depression, loss of appetite, digestive disturbance, loss of muscle power, listlessness, headaches, loss of vigor, nervousness, vague aches and pains, sleeplessness and irritability; and that the article contained hormonal activity equivalent to therapeutically significant amounts of testosterone. The labeling of the article was false and misleading by reason of such representations.

Fem-Tone. 502 (a)—the name by which the article was designated and certain statements and graphic matter in the labeling of the article when shipped represented and suggested that the article would restore sexual desire in women; that the article would be an adequate and effective treatment for fatigue, loss of appetite, nervousness, dizziness, headaches, vague aches and pains, weakness, mental depression, and sleeplessness; and that the article contained hormonal activity equivalent to therapeutically significant amounts of estrone. The labeling of the article was false and misleading by reason of such representations.

PLEA: Guilty.

DISPOSITION: 11–4–54. $1,000 fine.

4656. **Alpha tablets.** (F. D. C. No. 37524. S. No. 4–782 M.)

QUANTITY: 9 300-tablet btls. and 31 100-tablet btls. at Joliet, Ill.

SHIPPED: 11–3–54 and 11–16–54, from Detroit, Mich., by Wolverine Laboratories.

LABEL IN PART: (Btl.) "Alpha Tablets As An Aid In The Relief Of Pain and Discomfort Associated With Arthritis And Rheumatism * * * Each Tablet Contains Acetylsalicylic Acid, formulated in a base of organic Calcium and Alfalfa."

ACCOMPANYING LABELING: A placard entitled "Alpha Tablets For Rheumatism On Sale Here!" and pamphlets entitled "Alpha Tablets for the immediate relief of Arthritis."

LIBELED: 12–20–54, N. Dist. Ill.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for arthritis and rheumatism and that the article was a source of ingredients capable of healing and extending one's life; and, 502 (e) (2)—the label of the article failed to bear the common or usual name of each active ingredient.

DISPOSITION: 3–10–55. Default—destruction.

4657. Herb tea. (F. D. C. No. 36506. S. No. 51–080 L.)

QUANTITY: 386 cartons at Passaic, N. J., in possession of Sun-Gal Tea Co.

SHIPPED: 3–23–54, from New York, N. Y. (return shipment).

LABEL IN PART: (Carton) "Sun-Gal Brand Herb Tea * * * Sun Gal Herb Tea is made of—Alfalfa, Red Clover Blossoms, Raspberry Leaves, Strawberry Leaves, Peppermint Leaves, Linden Blossoms and Leaves, Mate, Chamomile Flowers, Papaya Leaves and Fennel Seeds. * * * 4 oz. net weight * * * prepared for and distributed by Sun-Gal Tea Co. 193 Jefferson Street. Passaic, N. J."

ACCOMPANYING LABELING: Leaflets designated "Perk Up! Drink To Your Health Sun-Gal Brand Herb Tea."

RESULTS OF INVESTIGATION: The article had been originally packaged and labeled by the Sun-Gal Tea Co. for retail sale. In addition, the above-mentioned leaflets had been printed locally for Sun-Gal Tea Co.

LIBELED: 4–14–54, Dist. N. J.

CHARGE: 502 (a)—when the article was shipped, its carton label and accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for arthritis, purifying the blood stream, strengthening children, benefiting the urinary organs, giving tone to the stomach, inflammations, nervous disorders, and catarrhal disorders.

DISPOSITION: 7–22–54. Consent—claimed by Sun-Gal Herb Tea Co. and relabeled.

4658. Garlex. (Inj. No. 274.)

COMPLAINT FOR INJUNCTION FILED: 3–12–54, N. Dist. Tex., against Walter Scott Roberts and Gertrude A. Roberts, associates in the operation of Texas Liquid Garlic Co., at Mineral Wells, Tex., to enjoin such individuals from the interstate shipment of *Garlex* in a misbranded condition.

LABEL IN PART: (Btl.) "Roberts Garlex An Extract of Garlic (Succus Allii Sativi) Compounded from Fresh Garlic Bulbs, Glycerine, and Mineral Wells Water by a Cold Process."

ACCOMPANYING LABELING: Pamphlet headed "Reprint from North American Journal of Homeopathy, May, 1944"; a pamphlet headed "Clinical Studies With Allium Sativum (Garlic)" bearing a footnote "Reprint from the New York Physician, September, 1937"; a leaflet headed "Therapeutic Digest" beginning with the words "Therapeutic Effects of Garlic"; and leaflets headed "On the Physiologic Action of Garlic (Allium Sativum)," "High Blood Pressure," and "Special Recommendations for Distemper"; copies of a letter addressed "To Whom It May Concern" dated February 19, 1950, and signed by A. M. Patterson, M. D.; and a letter dated September 28, 1953, addressed to William H. Stoker, Schenectady, N. Y., and signed by G. A. Roberts for Texas Liquid Garlic Co.

CHARGE: That the defendants had been and still were engaged in distributing, selling, and introducing into interstate commerce quantities of *Garlex* misbranded under 502 (a) by reason of false and misleading representations in its labeling that the article was adequate and effective in the treatment of gastrointestinal symptoms accompanying arteriosclerosis and hypertension by inhibiting intestinal putrefaction and formation of toxic products; that it was adequate and effective in the treatment of acute, subacute, and chronic diarrhea, enterocolitis, dysentery, digestive insufficiency, gastrointestinal dyspepsia,

anorexia, excessive intestinal fermentation, meteorism, and intestinal colic and subjective symptoms in arteriosclerosis due to gastrointestinal disturbances; that the article was adequate and effective in the treatment of tuberculosis, diarrheas from infectious diseases such as diphtheria, scarlet fever, and tuberculosis, hypertension accompanied by intestinal toxemia and marked reduction in blood pressure, subjective symptoms of dizziness, headache, thoracic oppression, and hypertension with arteriosclerosis unaccompanied by intestinal toxemia; that the article was adequate and effective as a nerve tonic, as a prophylactic for pneumonia, diphtheria, typhus, and tuberculosis, and as an expectorant in respiratory infections, especially those of the dry, hacking type, and in pulmonary tuberculosis and acute and subacute conditions of the upper respiratory tract; that the article would increase the red blood cell count; that the article was adequate and effective in the treatment of chronic asthma, bronchitis, nervous and spasmodic coughs, including whooping cough, neurasthenia, nervous insufficiency, round and thread worms, renal calculus, renal colic; typhoid and similar fevers, infantile diarrhea, septic throats, ozena, otorrhea, goiter, capillary bronchitis, fetid bronchitis, bronchiectasis, asthma, cholecystitis, intestinal catarrh, colitis, high blood pressure, hardening of the arteries, pains in left arm and side, and distemper in dogs, cats, and kittens; that the article would effect rapid elimination of toxins from the body, soothe inflamed organs and nerves, reduce fever, disinfect the entire toxin-infected system, and act as an antiseptic or intestinal antiseptic; and that the article would cause paralysis of worms and kill ascarids.

DISPOSITION: 4–5–54. The defendants having consented, the court entered a decree permanently enjoining the defendants from introducing into interstate commerce *Garlcæ* or any similar article which bore a label, or was accompanied by labeling, containing the false and misleading representations complained of.

4659. Roto-View Lamp device. (F. D. C. No. 36663. S. Nos. 18–599/600 L.)

INFORMATION FILED: 12–28–54, S. Dist. Calif., against Karl von Schilling, Los Angeles, Calif.

SHIPPED: Between 8–1–52 and 3–19–53, from California to Arizona.

LABEL IN PART: "Roto-View Lamp Econolite Corp. 3517 W. Washington Blvd. Los Angeles, Calif."

ACCOMPANYING LABELING: Charts entitled "Colour Feeding Your Glands," "Karl von Schilling's Astro-Biology Combined with Climatology—How to Determine *Your* Color * * * Need," and "Color Psycho-Somatics Special Chart for the Study of Color by Karl von Schilling," and leaflets entitled "Color Psycho-Somatics by Karl von Schilling."

RESULTS OF INVESTIGATION: The device, due to an internal mechanism consisting of a 100-watt light bulb located within a rotating cylinder of colored plastic strips, emanated a variety of colored light rays from a window in its outer shell.

CHARGE: 502 (a)—the labeling of the device when shipped contained false and misleading representations that colored light emanating from the device and shining upon the skin would affect the choroid, pituitary gland, brain, pineal gland, parathyroid gland, thyroid gland, thymus gland, heart, mammary gland, kidney, stomach, liver, spleen, pancreas, bowels, abdominal viscera, ovary, bladder, uterus, prostate gland, suprarenal gland, testicle, genitourinary and pelvic viscera, and other organs of the body; that colored light emanating

from the device and applied to the skin would be absorbed by the skin, taken up by the various organs of the body, feeding them and effecting health; that ill health would result from malnutrition of color rays; that, by flooding color from the device over various specified areas of the body, various specified internal organs would be affected through the medium of the blood and nerves; that the important viscera may be caused either to dilate or contract by application to the skin of various colors of the spectrum; that various color combinations, depending upon the date of one's birth, would aid the body in distress; that red color emanating from the device would heal asthma, failing sight, deafness, lung and bronchial trouble, colds, chills, obesity, fatty degeneration of heart, low blood pressure, dropsy, loss of appetite, and nervousness; that orange color emanating from the device would effect restoration to normal function; that yellow color emanating from the device would effect restoration of digestive and tissue tone; that green color emanating from the device would be a tonic for nerves and digestion; that blue color emanating from the device would heal venereal diseases, pubic rashes, high blood pressure, boils, neuralgia, sciatica, lumbago, rheumatism, rheumatoid arthritis, osteoarthritis, skin eruptions, ulcers, fevers, circulatory disorders, hardening of the arteries, and toxemia; and that violet color emanating from the device would be anesthetic, relaxing, and uplifting.

PLEA: Nolo contendere.

DISPOSITION: 4–18–55. Defendant sentenced to 90 days in jail.

4660. Vitozone ozone generator device. (F. D. C. No. 37281. S. Nos. 85–616/7 L.)

QUANTITY: 1 device at Sheridan, Wyo.

SHIPPED: During May or June 1954, from Billings, Mont., by Luther J. Martin.

ACCOMPANYING LABELING: Booklets designated "Ozone God's Gift To Humanity No. 3 * * * by J. H. Effenberg" and "Better Health and Better Living," and leaflets designated "Vitozone The *Only* Ozone Generator with so many EXCLUSIVE practical features" and "Ozone Instructions."

LIBELED: 10–8–54, Dist. Wyo.

CHARGE: 502 (a)—the accompanying labeling of the device when shipped contained false and misleading representations that the device was effective in the treatment of arthritis, nephrolithiasis, cholelithiasis, acute and chronic inflammatory conditions, asthma, diseased body cavities, including the pleural cavity, peritoneal cavity, bladder, urethra, intestines, impure blood, chlorosis, anemia, nervous prostration, tuberculosis of the skin, diphtheria, scarlet fever, infectious disease, tuberculosis, carbon monoxide poisoning, pneumonia, gas poisoning, whooping cough, amebic dysentery, Bright's disease, dropsy, and insomnia.

DISPOSITION: 12–14–54. Default—destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4654) Injunction issued. Contains opinions of the courts.
[2] (4641, 4658) Injunction issued.

[2] (4641, 4658) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1956

D. D. N. J., F. D. C. 4661–4680

Issued June 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4661–4680

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced or delivered for introduction into, or while in, interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or summary judgment; (2) criminal proceedings which were terminated upon pleas of nolo contendere or guilty and, in one case, upon a verdict of guilty; and (3) injunction proceedings in which decrees of injunction were entered upon default or consent of the defendants or after trial. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms or individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., June 7, 1956.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 4661, 4662, 4664; sale under name of another drug, No. 4673; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4662; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4662.

384842—56——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4661–4680

Adulteration, Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality and purity fell below the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality fell below, that which it purported or was represented to possess; and, Section 501 (d), the article was a drug, and a substance had been (1) mixed with the article so as to reduce its quality or (2) substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient including the quantity, kind, and proportion of any alcohol contained therein; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and, Section 502 (i) (3), the article was offered for sale under the name of another drug.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

4661. Drug for treatment of stomach disorders, hyperacidity, and ulcers. (Inj. No. 166.)

COMPLAINT FOR INJUNCTION FILED: Between 2–5–48 and 3–25–48, Dist. Minn., against Joseph E. McCoy, Thief River Falls, Minn., to enjoin the interstate shipment of a misbranded drug consisting of a suspension of bismuth subnitrate in a solution of water, sugar, alcohol, pepsin, and orange flavoring material.

CHARGE: The complaint alleged that the defendant had been and still was introducing into interstate commerce the above-described drug, which was misbranded as follows:

502 (a)—the labeling represented that the drug was efficacious in the cure, mitigation, and treatment of stomach disorders, hyperacidity, and gastric ulcers, whereas it was not effective for such purposes;

502 (e)—the label of the drug failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of the alcohol contained therein; and,

502 (f) (1)—the labeling of the drug failed to bear adequate directions for use since the labeling contained no reference to the disease conditions for which the drug was intended.

The complaint alleged also that the defendant had been repeatedly warned that the drug shipped by him in interstate commerce was misbranded within the meaning of the law; that the only effect of such warnings had been to cause the defendant to change the labeling so as to avoid one type of misbranding; and that in so doing, the defendant misbranded the drug in a different way, namely, by eliminating the false and misleading statements in the labeling, the defendant omitted all reference to the disease conditions for which the drug was intended and thereby misbranded the drug by failing to include in the labeling adequate directions for use.

DISPOSITION: 6–2–49. The defendant having filed an answer denying that the drug was misbranded and later having failed to pursue the matter further, an order of default was entered, together with an order permanently enjoining the defendant from shipping in interstate commerce the drug described in the complaint with or under the following labeling:

Joseph E. McCoy, M. D.
Thief River Falls, Minnesota
Specializing in Stomach Disorders
Hyperacidity and Gastric Ulcers
Take One Teaspoonful After Each Meal.
Shake Well Before Using

J. E. McCoy, M. D.
Thief River Falls, Minnesota
Take one Teaspoonful after each
meal. Shake well

J. E. McCoy, M. D.
Thief River Falls, Minnesota
(SHAKE WELL)
Take one teaspoonful after
each meal.

J. E. McCoy, M. D.
Thief River Falls, Minnesota
For Stomach Disorders, Hyper-
acidity and Gastric Ulcers
Directions: Take one teaspoonful
after each meal. Shake well be-
fore using.
Contains: Pepsin, Bismuth, Sub-
nitrate.
Alcohol–10 Per Cent–Net Contents–
8 Fluid Ounces

4662. Amphetamine sulfate tablets. (F. D. C. No. 35600. S. Nos. 72–608 L, 86–517 L, 86–524 L.)

INFORMATION FILED: 2–3–55, S. Dist. Fla., against Ledyard H. DeWees, Coral Gables, Fla.

SHIPPED: Between 4–10–54 and 6–9–54, from Florida to Maryland and Ohio.

RESULTS OF INVESTIGATION: The drug was shipped in unlabeled bottles.

CHARGE: 502 (b) (1) and (2)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e) (2)—the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and it failed to bear a label con-

taining the common or usual name of each active ingredient; and, 502 (f) (1) and (2)—the labeling of the article failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

PLEA: Nolo contendere.

DISPOSITION: 3–11–55. Defendant fined $300 and placed on probation for 1 year.

4663. **Supra Vite.** (F. D. C. No. 37528. S. No. 8–142 M.)

QUANTITY: 5 cases, 24 pkgs. each, at Kansas City, Mo.

SHIPPED: 11–19–54, from Glendale, N. Y.

LABEL IN PART: (Pkg.) "Supra Vite Special Now Biotin and K Added B–12 Increased An Improved Highly-Concentrated Food Supplement! Formulated in a base of alfalfa, parsley, watercress, cabbage, and brewers yeast concentrates. This package contains 122 multiple-vitamin capsules and 122 multiple-mineral tablets. Four red vitamin capsules and four mineral tablets (suggested daily intake) supply the following amounts and proportions of the minimum adult daily requirements."

LIBELED: On or about 12–20–54, W. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the article when shipped and while held for sale failed to bear adequate directions for use in the treatment of arthritis, coughs, and high blood pressure, which were the conditions for which the article was offered orally by Marie Carsil at Kansas City, Mo., on 11–6–54, while promoting the sale of the article to persons understood by her to be prospective purchasers.

DISPOSITION: 2–16–55. Default—destruction.

4664. **Rival herb tablets.** (F. D. C. No. 37570. S. No. 6–264 M.)

QUANTITY: 22 doz. 100-tablet boxes at Cleveland, Ohio.

SHIPPED: 11–1–54, from Detroit, Mich., by Rival Herb Co.

ACCOMPANYING LABELING: A leaflet entitled "Rival Herb Tablets."

RESULTS OF INVESTIGATION: The article was a brown sugar- and lime carbonate-coated tablet containing vegetable drugs, including emodin-bearing drugs.

LIBELED: 1–4–55, N. Dist. Ohio.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article would effectively regulate the bowels, stimulate liver and urinary action, and improve the appetite, and that it was an adequate and effective relief for all types of constipation, headaches, biliousness, dyspepsia, colds, and conditions caused by or associated with constipation; 502 (e) (2)—the label did not bear a statement of the active ingredients of the article; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use, in that the directions on the labeling provided for the taking of the article by both adults and children at regular intervals over an indefinite period of time, and such directions are inadequate for the use of a laxative drug; and, 502 (f) (2)—the labeling of the article failed to bear such adequate warnings against unsafe duration of administration, in such

manner and form, as are necessary for the protection of users, in that the labeling of the article contained the warning "To avoid any possibility of forming the laxative habit this preparation should not be taken continuously unless required," which warning was inadequate in that it failed to warn that frequent or continued use of the article under any circumstances may result in dependence upon laxatives to move the bowels.

DISPOSITION: 1–21–55. Default—destruction.

4665. Rectal suppositories. (F. D. C. No. 37569. S. No. 12–112 M.)

QUANTITY: 13,232 *rectal suppositories* in paper bags at New York, N. Y., in possession of Columbia Medical Supply.

SHIPPED: 11–3–54, from Jersey City, N. J., by G & W Laboratories, Inc.

LABEL IN PART: (Bag) "1,000 Special Formula Suppositories Shape: Rectal."

ACCOMPANYING LABELING: Loose box labels containing the following printed matter: "Columbia Blue-Gray Rectal Suppositories One Dozen Columbia Medical Company Distributors New York, N. Y. These suppositories afford soothing relief from discomfort of bleeding, itching and protruding piles. Directions Before using, spread a little mineral oil or vaseline over top of suppository. Then insert as deeply, as possible, morning and night. If necessary, insert also during the day. If condition persists, consult a physician. Be sure to keep in a cool, dry place. Each suppository contains: Bismuth Subiodide, Bismuth Subcarbonate, Zinc Oxide, and Boric Acid in a bland base."

RESULTS OF INVESTIGATION: The suppositories were to be repackaged by the consignee into boxes labeled as described above.

LIBELED: 1–11–55, S. Dist. N. Y.

CHARGE: 502 (a)—the box labels accompanying the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for bleeding and protruding piles and was safe for use in the treatment of bleeding piles; 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use; and, 502(f)(2)—the labeling of the article when shipped and while held for sale failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form, as are necessary for the protection of users, in that its labeling failed to warn that the article should not be used in case of rectal bleeding since rectal bleeding may indicate serious disease.

DISPOSITION: 2–25–55. Consent—claimed by Columbia Medical Laboratories, New York, N. Y., and relabeled.

4666. Uranium ore. (F. D. C. No. 37335. S. Nos. 85–866 L, 10–222 M.)

QUANTITY: 2,100 lbs. of *uranium ore* contained in unlabeled plastic sacks on the floor, on the walls, and on two full-length benches of a 16x7x7 ft. room designated as the Uranium Tunnel in Lone Rock, Wis.

SHIPPED: During April 1954, from Arizona, by Kenneth Crook.

ACCOMPANYING LABELING: Tear sheet designated "Arthritics Seek Cure In Radioactive Mines" taken from the July 7, 1952, issue of Life Magazine; letter dated "July 7, 1954" signed "Kenneth Crook"; letter dated "April 29, 1954" signed

"Mrs. R. S. Marshall"; letter dated "April 29, 1954" signed "Jean Steck P. O. Box 548, Prineville, Ore." letter undated signed "Robert Warmbier Clifton, Illinois," and letter undated signed "Maurice Warmbier Clifton, Illinois."

LIBELED: 1–14–55, W. Dist. Wis.

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article provided an adequate and effective treatment for arthritis, "other chronic diseases," multiple sclerosis, bursitis, and deafness; and, 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use in the treatment of the diseases and conditions for which it was intended, namely, arthritis, "other chronic diseases," multiple sclerosis, bursitis, and deafness.

DISPOSITION: Victor H. Baker, Lone Rock, Wis., the owner of the article, appeared as claimant and filed an answer admitting that the article was transported unlabeled in interstate commerce but denying that the article was misbranded as alleged in the libel. Thereafter, a motion for summary judgment was filed by the Government and was granted by the court on 6–24–55, on the ground that there was no genuine issue as to any material fact. On the same day, the court entered a judgment of forfeiture and ordered that the article be destroyed.

4667. Various devices. (Inj. No. 257.)

COMPLAINT FILED: 10–2–53, N. Dist. Calif., against Electronic Medical Foundation, a corporation, San Francisco, Calif., formerly known as the College of Electronic Medicine, and against Fred J. Hart, Salinas, Calif., president of the corporation and in full charge of its operations, Dr. Thomas Colson, San Francisco, Calif., secretary-treasurer of the corporation and in charge of the corporation's diagnostic laboratory and electronic research division, and Dr. Charles J. Pflueger, Los Angeles, Calif.. a member of the corporation's board of trustees and executive committee.

NATURE OF BUSINESS: The complaint alleged that the defendants were actively promoting the distribution in interstate commerce of certain devices, namely, *Oscilloclast, Oscillotron, Regular Push Button Shortwave Oscilloclast, Sweep Oscillotron, Sinusoidal Four-in-One Shortwave Oscillotron, Galvanic Five-in-One Shortwave Oscillotron*, all of which are hereinafter referred to as the *Oscilloclast* and *Oscillotron type of device; Depolaray, Depolatron, Depolaray Chair, Depolatron Chair, Depolaray Junior, Electropad, New Depolaray Junior*, all of which are hereinafter referred to as the *Dipolaray* and *Depolatron type of device;* and other similar "therapeutic" devices, as well as certain devices designated as *Blood Specimen Carriers* and intended for use as component parts of a "diagnostic" device designated as the *Radioscope;* that, during the past 30 years, the defendants had been promoting the sale and distribution of the devices by such means as lectures, testimonials, case reports, leaflets, books and periodicals, all purporting to have a scientific basis; that the defendants' interstate promotional activities were divided into two major parts, namely, the sale of their "diagnostic" service and the distribution of their "therapeutic" devices; that the defendants maintained their "diagnostic" device, called a *Radioscope*, at their San Francisco office where practitioners who purchased or used defendants' "therapeutic" devices would have access to defendants' "diagnostic" service; that, for a fee, the defendants would accept and examine blood specimens taken from patients of such prac-

titioners and then furnish the practitioners with the "diagnostic" data allegedly obtained through the use of the *Radioscope;* and, that upon the basis of such "diagnostic" data, the practitioners would treat their patients by using the "therapeutic" devices previously obtained from the defendants.

NATURE OF DEVICES: The *Radioscope* was represented as a "tuning apparatus" by which defendants asserted it was possible to distinguish the allegedly characteristic radio frequencies associated with different diseases. The *Radioscope* was a box containing dials, lights, and wires, and a slot in which would be placed a *Specimen Carrier* of filter paper bearing dried blood of a patient. When the *Radioscope* was used to "diagnose" disease, metal plates that were connected to the box were held by a person who was designated as the "reagent" and who was supposed to serve as a detector for the presence of radiations allegedly emanating from the dried blood in the *Specimen Carrier.* The "reagent's" part was passive. The operator would stroke the abdomen of the "reagent" with a plastic wand and determine whether or not the wand would "stick" on a particular spot on the abdomen. If the wand did "stick," that was supposed to be a manifestation of an "electronic reaction," and the operator allegedly could determine thereby whether the "electronic reaction" was one of health or disease, and if the "reaction" was one of disease, he allegedly could further determine its intensity, kind, location, and significance. The "reactions" which the operator allegedly elicited with the wand were supposed to vary according to whatever disease may be present in the person from whom that blood sample was taken, even though that person may be anywhere in the world. The ability of the blood sample to emanate these so-called radiations allegedly would last several weeks from the time the blood originally was drawn and allegedly registered the condition of the patient as of the time it was drawn. The sample allegedly reflected the presence of disease in any part of the body.

The "reactions" obtained from a blood specimen through a *Radioscope* examination were allegedly used for diagnosing the patient's condition. Such diagnostic data were recorded by defendants on a sheet entitled "Electronic Blood Chemistry Report," and interpreted by defendants on a sheet identified as "Dial Settings and Indicated Toxins." After filling out such sheets, defendants would send them together with recommendations for treatment to the practitioner who had submitted the blood specimen and who used this data as a basis for treating his patient with "therapeutic" devices obtained from the defendants.

The therapeutic qualities of defendants' devices (in their various models and combinations) were alleged to rest upon the representation that such devices produced certain low power radio waves and low frequency alternating magnetic energy which, when applied to the body, would "normalize" disease tissue thereby correcting disease conditions.

ACCOMPANYING LABELING: Literature entitled "Extension Bulletin No. 7," "Depolatherm, Depolatron, Depolaray Procedure," "Electronic Medical Digest—Summer 1950," "Shortwave Oscilloclast Oscillotron," "Extension Bulletin No. 6," "Improved Experimental Oscillotron Instructions," "Electronic Medical Digest—May–June, 1947" (This item was incorporated by reference in "Electronic Medical Digest—Summer 1950"), "Dial Settings and Indicated Toxins," "Suggested Shortwave Oscilloclast Treatment," "Information Sheet," "Electronic Blood Chemistry Report," and certain envelopes bearing statements relating to the *Blood Specimen Carriers.*

CHARGE: The complaint alleged that the *Depolaray* and *Depolatron type of device* and the *Oscilloclast* and *Oscillotron type of device* were misbranded under 502 (a) as follows:

1. The labeling of each such device created the false and misleading impression that the device was an outstanding therapeutic agent valuable in all kinds of disease conditions and was especially beneficial in the treatment of certain named disease conditions and abnormalities as follows:

(a) (*Depolaray* and *Depolatron type of device*) Abdominal pain, abscess on side of anus, abscessed teeth, arthritis of both knees, backaches, back sprains, baseball shoulders, Bell's palsy, black widow spider bite, bladder inflammation, boils, bronchitis, bruises (on various parts of body), bursitis, cancer of skin, carbuncles (including large carbuncle on back of neck), charley horse, colds, constipation, chronic cholecystitis, cystitis, ear trouble, eczema, eustachian tube infection, exhaustion, frequency of urination, fullness in perineum, gall bladder congestion, gallbladder irritation, gastric ulcers, gonad disease, hemorrhoids (including bleeding hemorrhoids) herpes zoster, high blood pressure, hip pointers, hornet stings, hyperthyroidism, hypertrophic (or inflamed) prostate, indigestion, inflammatory rheumatism, influenza (including intestinal "flu"), inguinal hernia, iritis, irritation of throat, loose coccyx, mastoiditis, maxillary sinus infection, middle ear infection, muscular rheumatism, neurasthenia, ovarian disorders, ovaritis, pain in eye, rectum, shoulder, or any part of body, phlebitis complicating varicose veins, poor elimination, pressure over coccyx, prostatic congestion, pulled muscle, septic sore throat, severe pain and swelling of right hip and thigh, shin splints, shingles, sinus infection, sore elbows, sore throat, sprained elbow, stiff ankle, stone bruise, swelling of head and face, tackle shoulder, tonsillitis, thrombosis of hemorrhoid, toxic condition, tumor of neck (and other tumors on other parts of body), ulcers (small), varicose ulcers, and varicose veins.

(b) (*Oscilloclast* and *Oscillotron type of device*) Abdominal distention due to gas, abdominal pressure, absence of secondary sex development, primary amenorrhea, anemia, angina pectoris, ankle swelling, anterior poliomyelitis, aphonia, appendix area tenderness, arrhythmia of heart, arthritis both shoulders, asthenia, asthma, bilateral auditory nerve degeneration, backache (including lumbar backache), back pain, bleeding gums, blotches on shoulder, breast tumors, cancer (including cancer of breast and stomach), cataract, cervix inflamed, cholecystitis, cholelithiasis, chorea, colds (including frequent and repeated colds), complexion sallow, confusion, constipation, spasmodic contraction of hands, coronary thrombosis, cough (including constant cough), cramps in lumbar region, deafness (including increasing deafness both ears), despondency, difficulty in breathing, discharge from vagina, discouraged condition, dizziness, double vision, easy fatigability, eczema (including that covering large body areas and of many years duration), enlarged and inflamed tonsils, enlarged prostate, epigastric and gallbladder region pain, extreme weakness, fatigue (including undue fatigue), feet purple, frequent urination, severe frontal headaches, gas on stomach after every meal, gastric ulcer or cancer, general skin ailments, glandular nodules swollen in both groins, gums sore, headaches (including migraine, daily, frontal, and headaches with vomiting), hemiplegia (including hemiplegia with muscle rigidity), high blood pressure, inability to take food or to work due to nausea, inability to walk due to infantile paralysis, indigestion, infantile paralysis, inflammation (in-

cluding inflammation of gallbladder, ovary, kidneys, bladder, and other parts of body), insomnia, irritability, kidney colic, lassitude, liver area pain, loss of weight (including continued loss of weight), mental exhaustion, muddy complexion, multiple neuritis, nausea and vomiting (including frequent and continued nausea and vomiting), nervous breakdown (including frequent and repeated nervous breakdowns), general nervous exhaustion, nervousness, neuritis in head, neck, shoulders, and arms, night sweats, pain (including severe pain and nocturnal pain) in various parts of body (such as eyes, jaws, spine, teeth, over right kidney, mediastinal area, joints of right hand, etc.), paralysis both legs, pleurisy with effusion, poor vision, pressure in back of head, rales over both lungs, rapid heart, restless sleep, retarded reflexes, rheumatism of various parts of body (including shoulders and legs), rigid spinal muscles, sensory disturbances, sinus infections and other sinus conditions, sore throat, spastic neuritis including muscle spasms, spastic paralysis since birth, staggering gait, stiffening of joints, stomach pain, stumbling gait, swollen lower legs, tachycardia, temperature elevated, thyroid gland enlargement, tiring easily and all the time, toenails loose, toenails missing, tuberculosis (including tuberculosis of both lungs verified by X-ray and tuberculin test), tumors (including fatty tumors), ulcers of leg (down to bone with heavy drainage), underweight, unnaturally thin condition, upset stomach accompanied by headache, uterine tumor, vomiting (including vomiting immediately after eating and periodic vomiting), weakness, uric acid, pyorrhea, X-ray burn, menopause, pain, amebiasis, typhus, radium burn, actinomycosis, influenza, common cold in fallopian tube, in bone, in pancreas, in brain, in nerve ending, in skin, in eye, in colon, in uterus, in breast, in liver, and in ovary, exostosis, inflammation, nicotine, hay fever, bovine TB, human TB in heart, in thyroid, in cervix, in stomach, in appendix, in ethmoid, in bladder, in tooth, in anthrum [sic], in eye, in tonsil, in breast, in ear, in uterus, in esophagus, in salivary gland, in intestine, in bone, in liver, in pancreas, in gallbladder, in skin, in kidney, in rectum, in ovary, in testicle, in prostate, in nerve ending, in brain, in frontal sinus, in lung, in lymph tissue, and in blood vessel, colisepsis, arthritis, pinworm, diphtheria, fatty tumor, carcinosis in spleen, in pancreas, in gallbladder, in liver, in nerve, in esophagus, in skin, in uterus, in thyroid, in stomach, in gum, in blood vessel, in intestine, in prostate, in kidney, in breast, in ovary, in lung, and in bone, urethral carbuncle, variola, neisserian [sic] in kidney, catarrh, eczema, necrosis, lues in leg sore, in stomach, and in prostate, gastric inflammation, lung congestion, general toxins, chondroma, connective tissue scar in bone, in soft tissue, in lung, and in adhesion, sarcosis in gallbladder, in liver, in prostate, in uterus, in ovary, in skin, in bone, in heart, in lymph, in breast, in intestine, in bone marrow, in stomach, in spleen, in brain, and in pancreas, ovarian cyst, Bang's disease, undulant fever, malta fever, streptotoxemia in colon, in pancreas, and in tooth, malaria, free pus, encapsulated pus, staphylotoxemia in eye, in tooth, in uterus, in tonsil, and in ovary, rhus toxicodendron, psora, fibroma, scarlatina, renal stones, chilblains, chickenpox, Rocky Mountain fever, malignancy, typhoid, impetigo, fermentation, putrefaction, adhesions, scar tissue, tropical ulcer, chancroid, rabies, mumps, hay fever, meningococcus, pellagra, fibroid, epilepsy, general toxemia, granuloma, warts, pain (inflammatory), anthrax, arteriosclerosis, autointoxication, bone exostosis, goiter, measles, migraine, general toxins fermentation, angioneurotic edema, carcinoma, epithelioma, acute inflammation, pneumococcemia, and pneumonia.

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2. The labeling of the *Oscilloclast* and *Oscillotron type of device* was false and misleading—

(a) In that the labeling represented and suggested that each such device in their various models were essentially alike and that the benefits allegedly obtained from one such model may reasonably be expected to be obtained from the others; and such labeling failed to reveal the following facts which were material in the light of such representations and suggestions:

(i) That some of the models were specifically designed to eliminate the presence of high frequency energy from the treatment face of the depolarizing electrodes, while other models were specifically designed to create and apply high frequency energy on the treatment face of the depolarizing electrodes.

(ii) That some of the models were specifically designed to give a depolarizer electrode output which was continuous in nature, while other models were designed to give a depolarizer electrode output which was pulsed in nature.

(iii) That "case reports" used in the current promotion of all of such models without differentiation were derived from the various models employing different characteristic electrical outputs and contradictory theories.

(iv) That the basic circuits of the various models were fundamentally different.

(b) In that the labeling represented and suggested that the so-called "Knight Circuit," as used in some models of the *Oscilloclast* and *Oscillotron* and not in others, enhanced the therapeutic value of such devices; and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That the "Knight Circuit" as used in the devices was simply a switch which continually turned on and off the electrical current coming into the devices, thereby creating electrical sparks that were common to all man-made mechanical or motor-driven switches.

(c) In that the labeling of each such device represented and suggested that various models of the *Oscilloclast* and *Oscillotron* derived their alleged therapeutic qualities from the generation and application of weak, interrupted radio waves ranging in frequency between 43.000 megacycles and 43.357 megacycles; and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That the atmosphere was continually carrying to and through the body of every human being interrupted radio waves of the same frequency range and order of magnitude generated by radio stations, mobile telephone units, etc.

(d) In that the labeling of each such device represented and suggested that the presence of a Tesla coil in the circuit was indispensable to the effective use of the *Oscilloclast* and *Oscillotron;* and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That some models of the devices did not have a Tesla coil in their circuits.

(e) In that the labeling represented and suggested that the shortwave energy generated by the *Oscilloclast* and *Oscillotron* was transmitted to the patient through a wire and electrodes (flat-plate or mesh or those designed to be inserted into body orifices) placed on or in certain areas of the body; and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That most of such shortwave energy was dissipated into the atmosphere and did not reach the body through such wire and electrodes.

The complaint alleged also:

1. That the *Depolaray* and *Depolatron type of device*, the *Oscilloclast* and *Oscillotron type of device*, and the *Blood Specimen Carriers* were misbranded under 502 (a) as follows:

(a) In that the labeling of each such device was false and misleading since it represented and suggested:

(i) That another device, the *Radioscope*, was capable of being effectively used to diagnose disease, whereas the *Radioscope* was not capable of being effectively used for such purposes.

(ii) That it would enable the doctor to know "just what is happening or is about to happen to body tissue," the cause of a particular disease, "to what extent the tissue is affected thus eliminating the need for exploratory surgical operations," and recommended a method of effective treatment, whereas the *Radioscope* was not capable of being effectively used for such purposes.

(iii) That it could detect diseases in the body even before symptoms of the disease appeared, making it possible to treat a condition such as tuberculosis or cancer, "before it has a fighting chance to wreak havoc in body tissue," whereas the *Radioscope* was not capable of being effectively used for such purposes.

(b) In that the labeling of each such device made the following false and misleading representations and suggestions:

(i) That the *Oscilloclast* and *Oscillotron type of device* produced these constant radio frequency outputs under the suggested conditions of use: Button 0=43.000 megacycles, Button 1=43.245 megacycles, Button 2=43.296 megacycles, Button 3=43.322 megacycles, Button 4=43.338 megacycles, Button 5=43.346 megacycles, Button 6=43.350 megacycles, Button 7=43.352 megacycles, Button 8=43.354 megacycles, Button 9=43.356 megacycles, and Button 10=43.357 megacycles.

(ii) That the *Oscillotron* energy pulsed approximately 110 times per minute.

(iii) That the *Galvanic Five-in-One Shortwave Oscillotron* may be used as a sinusoidal instrument.

(iv) That there was no shock hazard in the use of the *Galvanic Five-in-One Shortwave Oscillotron.*

(v) That in operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the volume range of current to the patient was from 0 to 15 milliamperes current, and the voltage range was 0 to 110 volts, direct current.

(vi) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the 0–5–X–3 shunt increased the current three times.

(vii) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the use of the rate sweep provided a treatment of 11 different rates per minute with 5½ seconds per minute devoted to each rate.

(viii) That the *Galvanic Five-in-One Shortwave Oscillotron* had a knob which controlled the phone jack receptacle marked "Pulse" in the lower right hand corner of the panel.

(ix) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the operator could increase the flow of treating energy through a given lesion by placing one flat-plate electrode connected with the treating jack on one side of the lesion and another flat-plate electrode connected with the return jack on the opposite side of the lesion.

(x) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, there was a simultaneous pulsing of the current in the depolarizer electrodes and in the shortwave flat plates which permitted the body cells undergoing treatment to rest 90 times per minute.

(xi) That the depolarizer electrodes of the *Galvanic Five-in-One Shortwave Oscillotron* produced a magnetic field of 80 gausses strength at their treating side.

(xii) That the low frequency electromagnetic energy output of the *Electropad* and the *Depolaray Junior* was 40 percent and 25 percent, respectively, of the energy output of the *Depolaray*.

(xiii) That the pulsing mechanism in the *Depolatherm Four-in-One*, also known as *Pulsating Infrared Depolatherm*, produced a change of voltage that created a wider range of infrared frequencies and a more effective instrument.

(c) In that the labeling of the *Blood Specimen Carriers* was false and misleading since it represented and suggested that such devices were capable of being used to carry disease radiations from a specimen of dried blood, which radiations allegedly could serve as an indication of the intensity, kind, location, and significance of any disease conditions present in the body from which the blood was taken, whereas such devices were not capable of being effectively used for such purposes.

2. That each device was misbranded under 502 (f) (1) in that its labeling failed to bear adequate directions for use; and,

3. That each device was adulterated under 501 (c) in that its strength differed from, and its quality fell below, that which it purported and was represented to possess.

DISPOSITION: On 3–15–54, the court, with the consent of the government and the defendants, entered the following decree:

ROCHE, *District Judge:* "Plaintiff having filed a Complaint for Injunction in the above-entitled cause to restrain the defendants from further alleged violations of the Federal Food, Drug, and Cosmetic Act; and defendants having filed an Answer; and upon the consent of plaintiff and defendants before trial on the merits;

"IT IS HEREBY ORDERED, ADJUDGED, and DECREED that the defendants, Electronic Medical Foundation, Fred J. Hart, Thomas Colson, and Charles J. Pflueger, and each and all of their officers, agents, servants, employees, and all persons in active concert or participation with any of them, be and they are hereby enjoined and restrained during the pendency of this

action and until the final determination thereof, from doing any of the following acts, directly or indirectly, in violation of Sections 301 (a) or 301 (k) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 331 (a) or (k)) with respect to any of the articles of device hereinafter enumerated—namely, the Oscilloclast, Oscillotron, Regular Push Botton Shortwave Oscilloclast, Sweep Oscillotron, Sinusoidal Four-in-One Shortwave Oscillotron, Galvanic Five-in-One Shortwave Oscillotron, Depolaray, Depolatron, Depolaray Chair, Depolatron Chair, Depolaray Junior, Electropad, New Depolaray Junior, and Blood Specimen Carriers—or any similar article of device allegedly capable of transporting blood for diagnosis by the Radioscope or of producing or measuring low power radio waves or electromagnetic energy or low frequency alternating magnetic energy, or any accessory, component, or part of any such article:

"(1) Introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce any such article of device which is:

(a) Misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any representation or suggestion in its labeling which conveys the impression that such article, or any of the other articles enumerated above, including the Radioscope, has value in the treatment or diagnosis of any kind of disease condition or has value in affecting any structure or function of the body of man or other animals; or

(b) Misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any other false or misleading representation or suggestion in its labeling; or

(c) Misbranded within the meaning of Section 502 (f) (1) of the Act (21 U. S. C. 352 (f) (1)) in that its labeling does not bear adequate directions for use because it does not contain a statement of all the purposes and conditions for which the articles are intended by the defendants; or

(d) Adulterated within the meaning of Section 501 (c) of the Act (21 U. S. C. 351 (c)) in that (1) its strength differs from or its quality falls below that which it purports or is represented to possess, or (2) it purports to produce or measure low power radio waves or electromagnetic energy or low frequency alternating magnetic energy which, when applied to the body, "normalize" disease tissue thereby correcting disease conditions, or (3) it purports to have diagnostic or therapeutic qualities; or

"(2) Doing any act or causing any act to be done with respect to any such article while such article is held for sale after shipment in interstate commerce which results in said article becoming misbranded or adulterated in any of the aforesaid respects; and

"IT IS FURTHER ORDERED that this injunction shall remain in effect until final disposition of this cause by this Court after trial on the merits; and

"IT IS FURTHER ORDERED that any trial on the merits shall be preceded by at least 90 days' notice to all parties with opportunity for utilizing the discovery and pre-trial procedure; and

"IT IS FURTHER ORDERED that at any such trial on the merits defendants' consent to this Decree shall not be deemed an admission against them, provided, however, that this Decree may be the basis for Contempt proceedings for any violation thereof; and

"IT IS FURTHER ORDERED that this Court expressly retain jurisdiction over the subject matter and parties herein in order that it may issue such further Orders and Decrees as may be necessary to the proper disposition of this proceeding."

4668. Voluptae device. (Inj. No. 288.)

COMPLAINT FOR INJUNCTION FILED: 3–11–55, S. Dist. Calif., against Hollywood Models, Inc., doing business under the fictitious name of Voluptae at Los Angeles, Calif., and against Lois Schwartz, also known as Anne Harris, president of the corporation.

CHARGE: The complaint alleged that the defendants were the interstate promoters and distributors of the device designated by the name of *Voluptae*,

which consisted of a large transparent plastic cup with a rubber gasket around the edge and a plastic vacuum pump attached to the cup. In use, the plastic cup was pressed against the chest so that it would enclose one of the breasts and the rubber gasket would form an airtight seal against the chest, after which the plastic pump was manipulated in a manner that created a partial vacuum inside the plastic cup.

The complaint further alleged—

(a) That the defendants were engaged in the interstate sale of the device through two principal techniques, i. e., (1) by a direct mail-order promotion initiated from their principal place of business at Los Angeles, Calif., and (2) by similar promotions initiated by distributors of the device at such cities as Chicago, Ill., Boston, Mass., and Cleveland, Ohio;

(b) That in conducting their direct mail-order promotion of the device from Los Angeles, Calif., the defendants (1) caused newspaper advertisements relating to the device to be printed in cities throughout the United States, (2) utilized extensive mailing lists which included the names and addresses of thousands of women residing in various parts of the United States who would likely be interested in the purchase of drugs and devices represented as effective for breast enlargement, and (3) caused to be mailed to women on such mailing lists certain circulars relating to the device, which circulars were designated as "Voluptae If You're Flat Chested" and "At Last! A Safe . . . New . . . Easy Way That Has Enabled Other Women to Develop a Full Firm Bust!";

(c) That when the defendants received orders for the device in response to the mail-order promotion, they caused the device to be shipped interstate from Los Angeles, Calif., to persons residing in various States throughout the country, and with each such shipment, the defendants enclosed a tie-on tag designated "Voluptae";

(d) That in conducting their sales promotion through distributors, the defendants would furnish the distributors with written, printed, and graphic matter consisting of copies of the above-mentioned advertising, circulars, and tie-on tag, photographs of certain "before and after" pictures of women, as well as copies of testimonial letters, physicians' statements, physicians' prescriptions, and physical therapists' letters; and that from such materials, the distributors would compile a Voluptae Sales Brochure;

(e) That the defendants caused bulk interstate shipments of the device to be made from time to time from Los Angeles, Calif., to such distributors; and

(f) That when the defendants caused the device to be introduced into interstate commerce, the labeling of the device included the above-mentioned circulars and tie-on tags and in some instances the materials used for the compilation of the Voluptae Sales Brochure.

The complaint alleged further that the defendants were violating Section 301 (a) of the Act by causing the introduction and delivery for introduction into interstate commerce of the device which was misbranded; that they were also violating Section 301 (k) of the Act by causing the association of the device with labeling consisting of the above-mentioned circulars, tie-on tags, and sales brochure, while the device was held for sale by the distributors after shipment in interstate commerce, which resulted in the device being misbranded. The device was alleged to be misbranded as follows:

502 (a)—the labeling of the device was false and misleading since it represented and suggested—

(a) That the device was effective for increasing the size of the breasts, for providing shape, growth, and expansion for underdeveloped breasts so that they would become full, round, and firm, and for improving the tone of the breast tissue, whereas the device was not effective for such purposes;

(b) That the device could be used safely without the supervision of a physician, whereas it could not be used safely without the supervision of a physician;

(c) That the directions for the use of the device would assure its safe use without medical supervision, whereas the labeling failed to reveal the material fact that the contraindications suggested in the labeling, including symptoms which were signs of early cancer, could only be detected by a competent physician and that the device should therefore never be used except upon the prescription of a physician;

(d) That physicians and surgeons commonly prescribed the use of the device in the regular course of their practice, whereas physicians and surgeons do not commonly prescribe the use of the device in the regular course of their practice; and

(e) That a number of physicians and surgeons whose letters were quoted in the labeling had approved the device as safe for use by women without the supervision of a physician, whereas such physicians and surgeons had not approved the device as safe for use by women without the supervision of a physician; and

502 (f) (1)—the labeling of the device failed to bear adequate directions for use, and the device was not eligible for an exemption from the requirement that its labeling bear adequate directions for use.

DISPOSITION: On 3–11–55, the court issued a temporary restraining order enjoining the defendants against the commission of the acts complained of. On 4–1–55, the defendants having given notice that they would not contest the case, the court entered a default decree of permanent injunction enjoining the defendants (1) from introducing into interstate commerce the *Voluptae device*, any similar device, or any device or drug offered for similar purposes, which would be misbranded as alleged in the complaint, and (2) from causing the association of labeling with any such device or drug while held for sale by a distributor after shipment in interstate commerce which would result in such device or drug being misbranded as alleged in the complaint.

DRUGS FOR VETERINARY USE

4669. Master Liquid (6 seizure actions). (F. D. C. Nos. 36060/2, 36144/8. S. Nos. 20–447/9 L, 83–856 L, 84–047/50 L.)

QUANTITY: 8 5-gal. cans and 172 1-gal. jugs at Belle Plaine, Carroll, Cherokee, Denison, George, Humbolt, Onawa, and Orange City, Iowa.

SHIPPED: Between 5–19–53 and 9–2–53, from Omaha, Nebr., by Master Laboratories.

LABEL IN PART: "Master Liquid * * * Ingredients: Sodium Thio-Sulphate; Beechwood Creosote; Guaiacol; Powdered Extract of Licorice; Sodium Hydroxide, 9%; Sodium Bicarbonate; Betanapthol; Oil of Anise; Sodium Phenosulfonate; Solution of Potassium Arsenite, (Arsenic as Arsenous Oxide, 0.75%); Nicotinic Acid."

ACCOMPANYING LABELING: Mimeographed letters entitled "Dear Friend and Dealer" and "Dear Dealers" and a leaflet entitled "Antibiotics Sulphas."

LIBELED: 10–28–53, 10–30–53, 11–23–53, and 11–30–53, N. Dist. Iowa; libels amended 10–29–54.

CHARGE: 502 (a)—the labels of the article when shipped contained misleading representations that the article was an effective remedy for diseases of swine; the label statement "Alkalinizes Slops composed of Oats, Barley or Grain Mixtures" was misleading in that it failed to reveal the material fact that such alkalinization was of no value or importance; and the labeling accompanying portions of the article contained false and misleading representations that the article was an adequate and effective treatment for disease in suckling pigs, "necro," scours, bacterial growth in the intestines, or conditions producing runty, unthrifty, and poor doing swine.

502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of "necro," scours, and general unthriftiness in pigs and hogs, which were the conditions for which the article was intended.

DISPOSITION: John E. von Dorn, the receiver of Master Laboratories, appeared as claimant in all six seizure actions. Upon motion of the claimant and with the consent of the United States attorney, the court, on 12–14–53, ordered the actions consolidated. On 9–16–54, the claimant filed an answer, admitting that the article was labeled as alleged in the libel but denying that the article was misbranded. Thereafter, the Government filed a motion for summary judgment on the grounds that there was no genuine issue of material fact.

On 1–6–55, the court, after consideration of written briefs and argument, handed down the following opinion sustaining the Government's motion:

GRAVEN, *District Judge:* "On December 14th, 1954, at the Federal Court House at Sioux City, Iowa, there came on for hearing the motions of the Libelant for summary judgment in the above entitled actions. F. E. Van Alstine, United States District Attorney appeared as attorney for the Libelant in support of said motions. John E. von Dorn appeared as attorney for the Claimant in resistance thereto. It was there agreed between the attorney for the Libelant and the attorney for the Claimant that the said motions be submitted on written briefs and arguments. The attorney for the Libelant thereupon submitted a written brief and argument on its behalf. On December 21st, 1954, the attorney for the Claimant submitted a written brief and argument on behalf of the Claimant, and the said motions were thereupon submitted to the Court and by it taken under advisement. The Libelant submitted affidavits in support of its motion for summary judgment. The Claimant submitted affidavits in connection with its resistance thereto.

"The Court now being fully advised in the premises finds:

1. The Master Laboratories was and is a co-partnership consisting of John E. von Dorn and Agnes C. von Dorn. John E. von Dorn is the liquidating trustee of said partnership which is the Claimant herein. The principal place of business of said partnership is in the City of Omaha, Douglas County, Nebraska.

2. For a number of years the Claimant has been engaged in selling in interstate commerce a liquid preparation styled and known as 'Master Liquid' or 'Master Liquid Hog Medicine.' The labels of the preparation contained claims or representations to the effect that the preparation would be beneficial and efficacious in the prevention or cure of a swine ailment commonly referred to as 'Necro.' The preparation is directed to be used in slop feed for swine.

3. On March 18th, 1949, the United States of America instituted an action in the Cedar Rapids Division of this District which action was Civil Action No. 325 in that Division. For convenience in reference that action will be referred to as Civil Action 325. That action was entitled as follows:

UNITED STATES OF AMERICA,
Libelant,
vs.
7 cans, more or less, 3 gallons each, and 3 cans, more or less, 5 gallons each of an article of drug labelled in part: "Master Liquid Hog Medicine"; and 43 leaflets entitled "Master Treatment For Brood Sows,"
Libelee.

4. In Civil Action 325 the Libelant claimed that the 'Master Liquid' preparation which was the subject matter of the action had been shipped in interstate commerce. The Libelant further claimed that the said liquid preparation was misbranded under the provisions of that portion of 21 U. S. C. A. Section 352 which provides: 'A drug . . . shall be deemed to be misbranded—(a) If its labelling is false or misleading in any particular.' The Libelant asked for the seizure and condemnation of the liquid preparation which was the subject matter of the action under the provisions of 21 U. S. C. A. Section 334. The Claimant in the present actions intervened as a Claimant in the action and contested the claims of the Libelant in regard to the liquid preparation. Starting on May 9th, 1950, a Court trial of substantial length was had as to the matters in issue between the Libelant and Claimant. The Libelant presented the testimony of eight expert witnesses. The Libelant's evidence included the results of tests of 'Master Liquid' in connection with 'Necro.' The Claimant presented the testimony of seven expert witnesses. The testimony of the expert witnesses covers over 400 pages of the transcript of the evidence. It was the claim of the Libelant that the swine ailment commonly referred to as 'Necro' was of bacterial origin. It was the claim of the Claimant that 'Necro' was 'caused primarily or that it follows at least from a nutritional deficiency.' (Transcript p. 4). It was the claim of the Claimant that alkaline solutions were of benefit in remedying the claimed nutritional deficiency and that the 'Master Liquid' was a preparation which would increase the alkalinity of the slop feeds fed to swine, and thereby prevent or cure 'Necro.' The evidence of the Libelant was to the effect that the Claimant's claim that 'Necro' was caused by nutritional deficiency was not well founded. The evidence of the Libelant was to the effect that the Claimant's claim that an alkaline solution would be of benefit in the prevention or cure of 'Necro' was not well founded. The evidence of the Libelant was to the effect that adding 'Master Liquid' to slop feed had the effect of decreasing the alkalinity of the feed.

"On May 20th, 1950, the Court filed its Findings of Fact, Conclusions of Law and Order for Judgment in Civil Action No. 325. In its Findings, the Court among other Findings made the following Findings:

Finding 11. * * * In common speech, swine are said to be suffering from "Necro" when they are afflicted with Necrotic Enteritis. Necrotic Enteritis is a disease caused by bacteria known as Salmonella Cholerasuis.

Finding 14. There is no credible or adequate scientific or medical foundation for any claim or representation that the use of Master Liquid Hog Medicine will prevent Necrotic Enteritis in swine.

Finding 15. There is no credible, adequate, scientific or medical foundation for any claim or representation that the use of Master Liquid Hog Medicine will cure Necrotic Enteritis in swine.

Finding 16. It clearly and satisfactorily appears that Master Liquid Hog Medicine is without efficacy or benefit in the treatment of Necrotic Enteritis in swine.

Finding 17. It clearly and satisfactorily appears that Master Liquid Hog Medicine is without efficacy or benefit in the prevention of Necrotic Enteritis in swine.

Finding 18. It clearly and satisfactorily appears that the ingredients of Master Liquid Hog Medicine, whether used separately or in combination, are without efficacy or benefit in the treatment or prevention of Necrotic Enteritis in swine however used or administered.

The Court further found that the Claimant in connection with the sale and shipment of the said liquid preparation made the claim or representation that

the same was of efficacy or benefit in the prevention of 'Necro' and that said claims or representations were both false and misleading.
5. The Court held that the said liquid preparation was misbranded under the provisions of 21 U. S. C. A. Section 352. On May 20th, 1950, the Court entered a decree condemning said liquid preparation and assessing the taxable costs in the sum of $1,503.73 against the Claimant. The Claimant then appealed the case to the United States Court of Appeals for the Eighth Circuit. On May 21st, 1951, there was certified to this Court by the Clerk of that Court a mandate of that Court docketed May 2d, 1951 (189 F. 2d 967), dismissing the appeal of the Claimant.
6. The present six actions were instituted in this District. Each of them relates to 'Master Liquid' shipped in interstate commerce to points in this District. In each action the Libelant claims that the particular shipment is misbranded under the provisions of 21 U. S. C. A. Section 352. In each action the Libelant asks that the particular shipment be seized and condemned under the provisions of 21 U. S. C. A. Section 334.
7. It is the claim of the Libelant in the present actions that the issues in these actions are the same as the issues in Civil Action No. 325 and that these issues were adjudicated adversely to the Claimant in that action and such adjudication is binding upon the Claimant in the present actions.
8. On page 11 of the brief and argument of the Claimant in the present actions the Claimant states as follows:

> The question of prior proceedings against the preparation "Master Liquid Hog Medicine" in the case tried at Cedar Rapids, Iowa, is not open to argument. That was a trial upon the merits between the same parties and would amount to an adjudication of the issues there presented. It is admitted that the parties are the same, the ingredients in the preparation are the same, but the label is not agreed to be the same or are the issues the same. The amended answer of claimant alleges new medical opinion and that inference made by claimant was to the extent that the product was of value in Nutritional "Necro" which is not the same as Necrotic Enteritis and points to a particular type of "Necro" (enteritis) to-wit: an enteritis from purely nutritional causes.

On page 2 of its amended answer in the present actions the Claimant states:

> Claimant further alleges that the article in question is an aid in the treatment of so-called "Necro" due to purely nutritional causes.

"In its resistance to the motions of the Libelant in the present actions the Claimant submitted the affidavits of three veterinarians. In their affidavits the affiants express the view that 'Necro' is also caused by nutritional deficiency and that 'Master Liquid' will be of benefit or aid in 'Nutritional Necro.' Two of the affiants testified at length and similarly in Civil Action No. 325. The Claimant claims that the theories as to the cause of 'Necro' change from time to time and the more modern theory is that 'Necro' is due to nutritional deficiency. In Civil Action No. 325 the evidence of the Libelant was to the effect that the theory that 'Necro' is due to nutritional deficiency was an older and discredited theory.
9. It is the finding and holding of the Court that the issue as to whether 'Necro' was due to bacteria as claimed by the Libelant or due to nutritional deficiency as claimed by the Claimant was presented and adjudicated adversely to the Claimant in Civil Action No. 325.
10. It is the finding and holding of the Court that the issue as to whether 'Master Liquid' has value or aid or benefit in the prevention or cure of 'Necro' was presented and adjudicated adversely to the Claimant in Civil Action No. 325.
11. In the present actions the labelling by the Claimant's admission does make the claim or representation that it is of value or aid or benefit in connection with 'Necro.'.
12. It is the finding and holding of the Court that the present labelling makes the same claim or representation that was adjudicated to be false and misleading in Civil Action No. 325.

13. It is the finding and holding of the Court that the Claimant in the present action is attempting to relitigate and re-try the same issues that were litigated and adjudicated in Civil Action No. 325. It is not permissible for the Claimant to do so. George H. Lee Co. v. Federal Trade Commission (8th Cir. 1940) 113 F. 2d 583; George H. Lee Co. v. United States (9th Cir. 1930) 41 F. 2d 460; Lee v. United States (10th Cir. 1951) 187 F. 2d 1005; United States v. 14 105 Pound Bags (D. C. Idaho 1953) 118 F. Supp. 837.
14. It is the finding and holding of the Court that there is no genuine issue of material fact in any of the present actions which is now subject to being litigated or tried.
15. It is the finding and holding of the Court that the Libelant is entitled to judgment in each of the present actions as a matter of law.

"It is hereby ordered that the motions of the Libelant for summary judgment in the present actions be and the same are hereby sustained and judgment shall be entered accordingly."

Pursuant to the above opinion, the court, on 1–6–55, entered decrees condemning the article and ordering its destruction. The claimant filed a motion for rehearing on 1–17–55 and a motion to amend findings and decrees on 1–28–55, both of which were denied by the court on 2–1–55.

4670. Hog Tabs. (F. D. C. No. 37529. S. No. 8–621 M.)

QUANTITY: 11 drums containing a total of 136,400 tablets and 21 250-tablet cans at Omaha, Nebr., in the possession of Standard Chemical Mfg. Co.

SHIPPED: 6–17–54, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Can) "Standard Hog Tabs An Intestinal Astringent Contain Potassium Permanganate and Copper Sulphate * * * Directions Dissolve one tablet in each gallon of water. * * * Give in the drinking water night and morning, * * * Feed hogs a milk of mill feed slop until they are well on the road to recovery."

RESULTS OF INVESTIGATION: The tablets had been shipped in bulk, and upon receipt by the consignee, a number of the tablets were repackaged into cans. Analysis showed that the tablets contained approximately 27 grains of copper sulfate and 3.6 grains of potassium permanganate per tablet.

LIBELED: 12–14–54, Dist. Nebr.

CHARGE: 502 (a)—the label of the article while held for sale contained false and misleading representations that the article was effective as an intestinal astringent for the treatment of "sick" hogs; and, 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 2–8–55. Default—destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4671. Bulk tablets. (F. D. C. No. 37404. S. No. 42–170 L.)

QUANTITY: 4 15,000-tablet drums at San Francisco, Calif.

SHIPPED: 8–24–54, from Cleveland, Ohio.

RESULTS OF INVESTIGATION: Examination showed that the tablets were contaminated with petroleum oil and were brownish in color and obnoxious in odor. It was assumed that the tablets became contaminated with petroleum oil while in transit.

LIBELED: 11–10–54, N. Dist. Calif.

CHARGE: 501 (d)—while in interstate commerce petroleum oil had been mixed with the article so as to reduce its quality; and, 501 (a) (2)—the article had been held under insanitary conditions while held for sale.

DISPOSITION: 1–10–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4672. Tu Tone capsules. (F. D. C. No. 37114. S. No. 72–050 L.)

QUANTITY: 4,000 capsules in a bulk container and 21 100-capsule btls. at Freeport, N. Y.

SHIPPED: Between 6–29–54 and 7–10–54, from East Newark, N. J., by Jabert Pharmacal Co., Inc.

LABEL IN PART: (Bulk container) "Tu Tone Capsules"; (btl.) "Pharmak Caution: Federal Law Prohibits dispensing without Prescription Dephar Each Capsule Contains 50,000 U. S. P. Units of Vitamin D."

RESULTS OF INVESTIGATION: The capsules in the bottles had been repackaged and relabeled by the consignee from the bulk shipment. Analysis showed that the article contained 25,000 units of vitamin D per capsule.

LIBELED: 10–6–54, E. Dist. N. Y.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which is purported and was represented to possess, namely, 50,000 units of vitamin D per capsule.

DISPOSITION: 11–16–54. Default—destruction.

4673. Rauwolfia serpentina (powder and tablets). (F. D. C. No. 37598. S. Nos. 10–213/9 M.)

QUANTITY: 6 100-lb. drums, 1 43-lb. drum, 139 100-tablet btls., 2 500-tablet btls., and 41 1,000-tablet btls. at Cedar Rapids, Iowa.

SHIPPED: Between 6–18–54 and 9–24–54, from New York, N. Y., by Prentiss Drug & Chemical Co.

LABEL IN PART: (Drum) "Pow. Rauwolfia Serpentina"; (btl.) "Raufia Encotes S. C. Light Orange Each tablet contains: * * * Rauwolfia Serpentina Alkaloids—0.75 mg. (Represented by approximately 100 mg. of the powdered whole root.) Paul Maney Laboratories Cedar Rapids, Iowa," "100 * * * Encotes Loten S. C. Gray Each tablet contains: * * * Rauwolfia Serpentina Alkaloids—0.75 mg. (As supplied by approximately 100 mg. of powdered whole root) * * * Paul Maney Laboratories Cedar Rapids, Iowa," and "Abten Sugar coated Pink Each tablet contains Rauwolfia Serpentina Alkaloids— 1.0 mg. (Represented by approximately 50 mg. powdered whole drug) * * * Paul Maney Laboratories Cedar Rapids, Iowa."

RESULTS OF INVESTIGATION: The article in the bottles was shipped from New York, N. Y., in bulk drums in powder form; and, after its receipt at Cedar Rapids, it was tableted, repacked into bottles, and relabeled by the consignee.

LIBELED: On or about 1–18–55, N. Dist. Iowa.

*See also Nos. 4667, 4671.

CHARGE: (Drums of powdered drug and tablets manufactured therefrom), 501 (d) (2)—when shipped, a substance, namely, the ground root of one or more species of *Rauwolfia* other than *Rauwolfia serpentina*, had been substituted in whole or in part for *Rauwolfia serpentina;* (drums of powdered drug), 502 (a)—the label statement "Pow. Rauwolfia Serpentina" was false and misleading since it represented that the article consisted wholly of *Rauwolfia serpentina*, which was not the case; (tablets manufactured from powdered drug), 502 (a)—the statement "Each tablet contains: * * * Rauwolfia Serpentina" borne on the bottle label while held for sale was false and misleading as applied to the article, which contained one or more species of *Rauwolfia* other than *Rauwolfia serpentina;* and (drums of powdered drug and tablets manufactured therefrom), 502 (i) (3)—the article was a drug which was not *Rauwolfia serpentina*, and, when shipped, was offered for sale under the name of another drug, namely, *Rauwolfia serpentina*.

DISPOSITION: 3–12–55. Default—destruction.

4674. **Adhesive bandages.** (F. D. C. No. 33768. S. Nos. 3–617 L, 12–613 L, 26–078 L, 26–408 L.)

INFORMATION FILED: 5–28–53, E. Dist. N. Y., against Gotham Aseptic Laboratory Co., Inc., Long Island City, N. Y.

ALLEGED VIOLATION: On 2–4–52, the defendant caused *adhesive bandages*, adulterated and misbranded as hereinafter described, to be delivered for introduction into interstate commerce.

LABEL IN PART: "Sterilized Handy Adhesive Bands Supreme First Aid Co., Inc. New York, N. Y."

CHARGE: 501 (b)—the quality and purity of the article when shipped fell below the standard for adhesive absorbent bandage set forth in the United States Pharmacopeia, in that it was not sterile but was contaminated with viable micro-organisms; and, 502 (a)—the label statement "Sterilized" was false and misleading.

PLEA: Not guilty.

DISPOSITION: The defendant filed a motion for a bill of particulars, which the court, on 4–26–54, granted in part. Thereafter, on 7–11–55, the defendant entered a plea of guilty; and, on 7–28–55, it was fined $500.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4675. **Colusa Natural Oil and Colusa Natural Oil Capsules.** (Inj. No. 172.)

COMPLAINT FOR INJUNCTION FILED: 8–26–48, S. Dist. Calif., against Colusa Remedy Co., a corporation, Los Angeles, Calif., and Chester Walker Colgrove, president of the corporation, to enjoin the interstate shipment of the above-mentioned articles misbranded under 502 (a).

LABEL IN PART: The labels of the articles are quoted in the findings of fact set forth below.

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*See also Nos. 4661, 4664–4668, 4673, 4674.

CHARGE: The complaint alleged that the defendants had been and were at the time of filing the complaint introducing into interstate commerce *Colusa Natural Oil* and *Colusa Natural Oil Capsules* which were misbranded under 502 (a) in that their labeling contained representations that the articles were efficacious in the treatment of psoriasis, eczema, poison ivy and poison oak, athlete's foot, leg ulcers, acne, itch, and open sores, whereas the articles were not efficacious for such purposes.

The complaint alleged further that the defendants and the Empire Oil & Gas Corp., predecessor in interest of Colusa Remedy Co., had a long history of violations of the Act; that a default decree of condemnation had been entered against a shipment of *Colusa Natural Oil* which was seized in July 1940, on the charge that it was misbranded by reason of false and misleading representations concerning its effectiveness for certain diseases including psoriasis, eczema, and athlete's foot (notices of judgment on drugs and devices, No. 380); that with respect to such shipment, criminal proceedings subsequently were instituted against the Empire Oil & Gas Corp. and its president, Chester Walker Colgrove, and were terminated upon pleas of nolo contendere (notices of judgment on drugs and devices, No. 1040); that, thereafter, the labels of the *Colusa Natural Oil* and *Colusa Natural Oil Capsules* were changed by omitting any reference on the labels to the diseases for which the articles were to be used, and, in lieu of such label references the dealers were supplied with illustrated circulars in which the articles were offered and recommended in the treatment and cure of psoriasis, eczema, leg ulcers, itch, and athlete's foot; that between June 1944 and the time of filing the complaint, over 150 seizure actions had been instituted against the articles, most of which actions had been terminated by the entry of default decrees of condemnation; that the defendants abandoned the use of the misbranded circulars after a period of time and resorted to the use of newspaper advertising to stimulate the sale of the articles; that the labels of the articles as advertised failed to bear adequate directions for use of the articles in the conditions for which they were advertised; that the Government, contending that the articles were thereby misbranded, instituted injunction proceedings resulting in the issuance of an injunction on 4–23–47, prohibiting the defendants from introducing the articles into interstate commerce unless their labels contained adequate directions for use in the treatment of all conditions for which the articles were prescribed, recommended, and suggested in advertising material disseminated or sponsored by or on behalf of the defendants (notices of judgment on drugs and devices, No. 3061); that following the issuance of the injunction, the defendants reverted to their original practices of referring to psoriasis, eczema, leg ulcers, and athlete's foot on the labels of the articles; that subsequently a number of seizure actions were instituted against the articles on the charge of misbranding by reason of false and misleading representations in the labeling concerning the efficaciousness of the articles in the treatment and cure of psoriasis, eczema, leg ulcers, athlete's foot and open sores; that such seizure actions were consolidated for trial in the Northern District of Iowa and tried between 11–13–47 and 11–18–47; that at the conclusion of the trial, the court held the articles to be misbranded as charged (notices of judgment on drugs and devices, No. 2922); that a contempt action charging the defendants with violation of the injunction of 4–23–47 was instituted on 10–3–47; and that after full consideration of the activities of the defendants, the court found the defendants guilty of criminal contempt (notices of judgment on drugs and devices, No. 3061).

DISPOSITION: Pursuant to the Government's request, an order to the defendants to show cause why a preliminary injunction should not be issued was entered by the court on 8–26–48. On 2–9–49, after a hearing in the matter, the court denied the request for a preliminary injunction. Thereafter, the case came on for trial before the court without a jury on the question of issuing a permanent injunction. The trial was concluded on 5–24–49, and on 6–8–49, the court handed down the following findings of fact and conclusions of law:

MATHES, *District Judge:*

FINDINGS OF FACT

"1. The defendant, COLUSA REMEDY COMPANY, INC., is a corporation organized and existing under the laws of the State of Nevada and has its principal place of business and office in Los Angeles, California.

"2. Defendant, CHESTER WALKER COLGROVE, was the president of defendant, COLUSA REMEDY COMPANY, INC., but has sold his interest in the firm and is no longer associated with its operations.

"3. At the conclusion of the trial in this cause, the case of *United States* v. *9 Bottles . . . 'Colusa Natural Oil' et al.*, 78 F. Supp. 721, (N. D. Iowa, 1947), was pending on appeal in the United States Court of Appeals for the Eighth Circuit.

"4. Defendant, COLUSA REMEDY COMPANY, INC., for some years has been introducing and delivering for introduction into interstate commerce articles of drug labeled 'Colusa Natural Oil' and 'Colusa Natural Oil in Capsules.' Said defendant will continue to ship such articles in interstate commerce unless restrained by this Court.

"5. The labeling of Colusa Natural Oil reads as follows:

COLUSA
Natural Oil

A natural unrefined petroleum oil intended for trial use in external treatment of symptoms of Psoriasis, Eczema, including Poison Ivy and Poison Oak, Leg Ulcers, Athlete's Foot, Acne and Itch. Due to the various causative factors, types, kinds and/or stages of the diseases above named, we do not represent that Colusa Natural Oil will cure, alleviate or relieve any one's particular case. We recommend its trial use and represent that thousands of doctors, druggists and users have written us telling of great benefit derived from its use in their cases. We want to help YOU and invite your trial use on the following guaranteed basis, viz: if it fails to alleviate or relieve your case to your entire satisfaction you may return the unused portion with sales slip showing return mailed within not more than six weeks after date of purchase and your money will be refunded. See directions for use on back label.

Net Contents 4 fl. oz.

COLUSA REMEDY CO.

1507 Wilcox Ave. Los Angeles, Calif.

DIRECTIONS

for external use of Colusa Natural Oil: Apply to affected parts and rub it in thoroughly morning and night. For open sores, saturate cotton pad with oil and bind on by gauze. Change to fresh dressing morning and night. For tender skin, oil can be diluted 50% with olive oil. Continue treatment four weeks, or longer if you believe it is helping you. In treatment of symptoms of Psoriasis, Eczema, Acne and leg ulcers we suggest you try Colusa Natural Oil capsules internally in conjunction with Colusa Natural Oil externally, pursuant to the trial offer terms and directions for use printed on labels of bottles containing Colusa Natural oil capsules.

To remove oil stains from linen, use Energine or other solvent before putting into water.

"6. The labeling of Colusa Natural Oil in Capsules reads as follows:

COLUSA

Natural Oil

A natural unrefined petroleum oil in capsules. Intended for trial use in internal treatment of symptoms of Psoriasis, Eczema, Acne, Leg Ulcers. Due to the various causative factors, types, kinds and/or stages of the diseases above named, we do not represent that Colusa Natural oil capsules will cure, alleviate or relieve any one's particular case. We recommend their trial use and represent that thousands of doctors, druggists and users have written us telling of great benefit derived from the use of Colusa Natural oil externally and/or Colusa Natural oil capsules internally in their cases. We want to help YOU and invite your trial use on the following guaranteed basis, viz: If they fail to alleviate or relieve your case to your entire satisfaction you may return the unused portion with sales slip showing return mailed within not more than six weeks after date of purchase and your money will be refunded. See directions for use on back label.

Net contents 200 capsules

COLUSA REMEDY CO.

1507 Wilcox Ave. Los Angeles, Calif.

DIRECTIONS

for internal use of Colusa Natural oil capsules. For adults, start with one capsule at bed time, then after 3 days change to one capsule after each meal. For children under ten, one capsule or its content squeezed into milk or water at bed time. Continue four weeks or longer if you believe they are helping the case being treated. In treatment of symptoms of Psoriasis, Eczema, Acne and Leg Ulcers, we suggest you try Colusa Natural oil externally in conjunction with Colusa Natural Oil capsules internally, pursuant to the trial offer terms, and directions for use, printed on the labels on bottles containing Colusa Natural oil in liquid form.

"7. The article, Colusa Natural Oil, is a crude, natural, unrefined seepage, petroleum oil. The article, Colusa Natural Oil in Capsules, consists of capsules each containing approximately .18 grams of Colusa Natural Oil.

"8. The labeling of Colusa Natural Oil in effect represents and suggests that it is beneficial and efficacious in the treatment, mitigation, and cure of psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, and open sores.

"9. The labeling of Colusa Natural Oil in Capsules in effect represents and suggests that it is beneficial and efficacious in the treatment, mitigation, and cure of psoriasis, eczema, acne, and leg ulcers.

"10. Psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, and open sores are diseases which manifest themselves on the surface of the human skin.

"11. Both the article, Colusa Natural Oil, and the article, Colusa Natural Oil in Capsules, are intended for use in the treatment, mitigation, and cure of disease in man.

"12. Colusa Natural Oil is not beneficial or efficacious in the treatment, mitigation, or cure of any of the disease conditions mentioned on its labeling.

"13. Colusa Natural Oil in Capsules is not beneficial or efficacious in the treatment, mitigation, or cure of any of the disease conditions mentioned on its labeling.

"14. Colusa Natural Oil and Colusa Natural Oil in Capsules, when taken or used as directed on their labeling or otherwise, separately or in combination, are worthless in the treatment, mitigation, or cure of any of the disease conditions mentioned on their labeling.

"15. The labeling of Colusa Natural Oil is false and misleading in the particulars and by reason of the facts hereinabove found.

"16. The labeling of Colusa Natural Oil in Capsules is false and misleading in the particulars and by reason of the facts hereinabove found.

CONCLUSIONS OF LAW

"1. This Court has jurisdiction over the subject matter in this case and over the parties thereto.

"2. The Complaint is dismissed as to CHESTER WALKER COLGROVE.

"3. This Court is not bound by the findings of fact in the case of *United States* v. *9 Bottles . . . 'Colusa Natural Oil' et al.*, 78 F Supp. 721 (N. D. Iowa, 1947) since that case is pending on appeal and the findings of fact therein are not now final.

"4. Colusa Natural Oil and Colusa Natural Oil in Capsules are drugs within the meaning of 21 U. S. C. 321 (g) (2).

"5. The articles, Colusa Natural Oil and Colusa Natural Oil in Capsules, are misbranded within the meaning of 21 U. S. C. 352 (a).

"6. Plaintiff's prayer for an injunction should be granted permanently restraining defendant, COLUSA REMEDY COMPANY, INC., from introducing or causing to be introduced into interstate commerce, and from delivering or causing to be delivered for introduction into interstate commerce, in violation of 21 U. S. C. 331 (a), any Colusa Natural Oil or Colusa Natural Oil in Capsules which is misbranded within the meaning of 21 U. S. C. 352 (a), and in particular which contains any labeling representing or suggesting that these products, used separately or together, are or might be beneficial or efficacious in the treatment, mitigation, or cure of psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, or open sores.

"7. Plaintiff is entitled to all costs properly taxable against the defendant, COLUSA REMEDY COMPANY, INC."

Pursuant to the above-mentioned findings of fact and conclusions of law, the court, on 6–8–49, entered a decree permanently enjoining the Colusa Remedy Co., its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with all or anyone or more of them from introducing into interstate commerce *Colusa Natural Oil*, *Colusa Natural Oil Capsules*, or any like products which are misbranded under 502 (a), and in particular which contain any labeling representing that the articles used separately or together are or might be beneficial or efficacious in the treatment, mitigation, or cure of psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, or open sores.

A motion for a new trial was filed by the Colusa Remedy Co., and on 9–19–49, was denied. A notice of appeal was filed by the company on 11–15–49, but no steps were taken thereafter to perfect the appeal. A stipulation subsequently was entered into between the parties agreeing to the dismissal of the appeal, and was approved by the court on 10–9–50.

4676. Lymphex and Tracel. (F. D. C. No. 35184. S. Nos. 38–376 L, 51–057/8 L, 56–602/3 L.)

INFORMATION FILED: 10–21–53, Dist. N. J., against H. Hall Marshall, t/a Consultants' Laboratories, Millington, N. J.

SHIPPED: Between 7–18–52 and 3–12–53, from New Jersey to New York, Maryland, and Tennessee.

LABEL IN PART: (Can) "Lymphex Myroxylon Bark Extract Osmotic Baths * * * Active Ingredients Lymphex Osmotic Baths contain a new extract of the myroxylon tree from one particular tropical environment. This extract also contains eucalyptol, nerolidol and cinnamein (used as extractors) and is combined with laurel sodium sulfonate (foaming and wetting agent) and sodium carbonate (water softener)"; (btl.) "Tracel Trace Element Mineral Concentrate Each Two Teaspoons Contain The Following Amounts: Cobalt

.15 mgs., Magnesium 2 mgs., Fluorine .1 mgs., Sodium 2.5 mgs., Copper 1 mg., Iodine .15 mgs., Nickel .015 mgs., Sulphur .25 mgs., Manganese 1.5 mgs., Chlorine .014 gms., Potassium .15 mgs., Zinc 1.5 mgs."

ACCOMPANYING LABELING: (Lymphex) Booklet entitled "Myroxylon Bark Extract New Type Osmotic Bath Therapy for Arthritis and Chronic Sinus Trouble" and various letters addressed by the defendant; (Tracel) leaflets entitled "National Disaster by Mineral Starvation" and "The Normal Diet Cannot Be Depended Upon for Adequate Vitamins–Minerals–Trace Elements."

CHARGE: *Lymphex.* 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article consisted essentially of an extract of myroxylon tree bark and that the article was an adequate and effective treatment for deep-seated infections, arthritis, sinusitis, bursitis, rheumatic fever, inflammatory rheumatism, sciatica, and many infections including those of a virus nature.

Tracel. 502 (a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article would be effective in the treatment of allergies and asthma; that it would be effective in the prevention of diabetes; that all of the minerals contained in the article were trace elements and are required in human nutrition; that a normal diet would not supply adequate vitamins, minerals, and trace elements; and that the human system cannot make use of vitamins without minerals.

PLEA: Not guilty.

DISPOSITION: On 5–11–54, the case came on for trial before a jury, and, at its conclusion, the jury returned a verdict of guilty. On 5–28–54, the court fined the defendant $500 on count 4 of the information relating to the Tennessee shipment of *Lymphex*, suspended the imposition of sentence on the other counts, and placed the defendant on probation for 1 year.

4677. Vitalitone device. (F. D. C. No. 37096. S. Nos. 80–428 L, 81–078 L.)

QUANTITY: 2 devices at San Francisco, Calif.

SHIPPED: 2–17–54 and 3–15–54, from Salt Lake City, Utah, by Park Mfg. Co.

LABEL IN PART: (Device) "Vitalitone Model B."

ACCOMPANYING LABELING: Booklets entitled "Vitalitone Application Placements For Various Conditions" and copies of a body chart showing points of application of the device to the body.

RESULTS OF INVESTIGATION: The *Vitalitone device* was a device for applying electric currents to the body.

LIBELED: 9–15–54, N. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article when shipped contained false and misleading representations that the article would provide an adequate and effective treatment for rheumatism, arthritis, "Charley horse," liver ailments, kidney ailments, paralysis, prolapsed colon, conditions affecting the female organs, angina pectoris, nervous indigestion, high blood pressure, low blood pressure, constipation, asthma, fallen arches, sinus conditions, hay fever, double chin, bags under the eyes, and for rejuvenating the busts.

DISPOSITION: 12–22–54. Consent—claimed by Walter F. Gertz, San Francisco, Calif., and relabeled.

4678. Voluptae device. (F. D. C. No. 36877. S. No. 58–204 L.)

QUANTITY: 51 assembled units and component parts for assembling 925 units at Chicago, Ill.

SHIPPED: 5–25–54, from Los Angeles, Calif., by aaRbee Plastic Co., at the direction of Hollywood Models, Inc.

ACCOMPANYING LABELING: Tags designated "Voluptae" for attaching to the assembled device; folders entitled "Voluptae" containing "before" and "after" photographs; and mailing sets, each containing a circular designated "Voluptae If You're Flat Chested" and a circular designated "At Last! A Safe . . . New . . . Easy Way That Has Enabled Other Women to Develop a Full Firm Bust" and a directions tag designated "Voluptae."

RESULTS OF INVESTIGATION: The interstate shipment described above consisted of unassembled component parts of the *Voluptae device.* These parts were shipped for delivery to Chicago, Ill., to Voluptae, Division of Permanent Stainless Steel, Inc., for assembly by that firm. Such firm also had the above-mentioned accompanying labeling produced locally at Chicago, using, in part, reproductions of printed and graphic matter originally supplied to it by Hollywood Models, Inc.

The assembled *Voluptae device* consisted of a plastic cup with a rubber gasket around its edge and a plastic vacuum pump attached to the cup. In use, the plastic cup was pressed against the chest so that it would enclose one of the breasts and the rubber gasket would form an airtight seal against the chest, after which the plastic pump was manipulated in a manner that created a partial vacuum inside the plastic cup.

LIBELED: 7–12–54, N. Dist. Ill.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped and while held for sale contained false and misleading representations that the device was effective in increasing the size of the breasts, providing shape, growth, and expansion for underdeveloped breasts so that they would become full, round, and firm, and for improving the tone of the breast tissues.

DISPOSITION: On 10–6–54, Hollywood Models, Inc., claimant, having requested removal of the libel action to the United States District Court for the Northern District of California, an order was entered directing such removal. Thereafter, Hollywood Models, Inc., withdrew its claim, and on 6–21–55, a default decree was entered providing for condemnation of the goods and delivery to the Food and Drug Administration.

DRUGS FOR VETERINARY USE*

4679. 3-Way Dog-Tone Tabs. (F. D. C. No. 35283. S. No. 66–173 L.)

QUANTITY: 58 cartons, 12 boxes each, at Oak Park, Ill.

SHIPPED: Between 2–16–53 and 4–26–53, from Addison, Mich., by Hickory Laboratories, Inc.

LABEL IN PART: (Box) "Hickory's * * * 3-Way Dog-Tone Tabs * * * 50 Tablets * * * An Effective Wormer Conditioner And Toner To Help Prevent And Relieve The Symptoms Of Colds And Distemper * * * Active Ingredients Areca Nut 2 grains; Sulphur; Sodium Hyposulphite."

ACCOMPANYING LABELING: Leaflets entitled "An Effective Wormer, Toner and Conditioner."

RESULTS OF INVESTIGATION: Analysis revealed that the article contained 1.5 grains of sulfur, 0.9 grain of sodium hyposulfite, and not more than 1.2 grains of areca nut per tablet.

LIBELED: 6–2–53, N. Dist. Ill.

*See also Nos. 4669, 4670.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was effective as a wormer, toner, and conditioner in the prevention and treatment of colds and distemper of dogs and cats; that it protects dogs from many common ailments; that it tones up system to resist disease; that it keeps dogs worm-free and in good condition; that it affords fast relief for symptoms of colds, distemper, fever, and common internal disorders; and that it was effective in the treatment of dogs sick with distemper, worms, diarrhea, cramps, fits, fever, etc.; and, in addition, the label statement "Areca Nut 2 grains" was false and misleading.

DISPOSITION: 2–9–55. Default—destruction.

4680. **Rockland Ol-Ar-Em.** (F. D. C. No. 37053. S. No. 75–478 L.)

QUANTITY: 1 40-gal. drum at Parsonsburg, Md.

SHIPPED: 6–1–54, from Newark, N. J., by Rockland Chemical Co.

LABEL IN PART: (Drum) "Active Ingredients: Menthol, Oil of Pine, Oil of Eucalyptus, Oil of Origanum Inert Ingredient: Filtered Feeding Oil."

LIBELED: On or about 8–14–54, Dist. Md.

CHARGE: 502 (a)—the drum label of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for colds and coryza in poultry.

DISPOSITION: 9–15–54. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4661 TO 4680

PRODUCTS

[1] (4674, 4676) Prosecution contested.
[2] (4661, 4668) Injunction issued.
[3] (4667) Injunction issued. Contains consent decree of injunction.
[4] (4675) Injunction issued. Contains findings of fact and conclusions of law.
[5] (4666) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4674, 4676) Prosecution contested.
[2] (4661, 4668) Injunction issued.
[3] (4667) Injunction issued. Contains consent decree of injunction.
[4] (4675) Injunction issued. Contains findings of fact and conclusions of law.
[5] (4666) Seizure contested.
[6] (4669) Seizure contested. Contains opinion of the court.

[1] (4674, 4676) Prosecution contested.
[2] (4661, 4668) Injunction issued.
[3] (4667) Injunction issued. Contains consent decree of injunction.
[6] (4669) Seizure contested. Contains opinion of the court.

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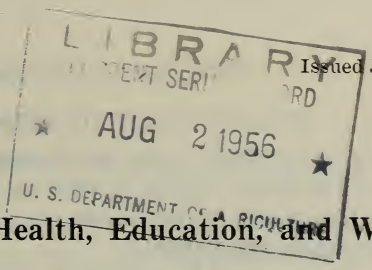

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4681–4720

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 11, 1956.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

4681. (F. D. C. No. 36649. S. Nos. 703 L, 56–698 L, 78–829 L.)

INDICTMENT RETURNED: 8–10–55, S. Dist. Ind., against **Miller Drugs, Inc., Terre Haute, Ind., Fred F. Miller (president), and Thurman H. Miller (secretary-treasurer of the corporation).**

CHARGE: Between 2–13–53 and 3–1–54, *tablets containing a mixture of sulfacetamide, sulfadiazine, and sulfamerazine* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by corporation to all 3 counts of information; by Fred F. Miller to 2 counts; and by Thurman H. Miller to 1 count.

DISPOSITION: 9–9–55. Fine of $150 against corporation, $200 against Fred F. Miller, and $100 against Thurman H. Miller, plus costs.

4682. (F. D. C. No. 37216. S. Nos. 40–233 L, 40–235 L.)

INFORMATION FILED: 2–10–55, Dist. Ariz., against **William B. Betty, t/a Buckeye Pharmacy, Buckeye, Ariz.**

CHARGE: Between 2–12–54 and 2–19–54, *tablets containing a mixture of sulfadiazine, sulfathiazole, and sulfamerazine* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 3–21–55. Fine of $500 and probation for 1 year.

4683. (F. D. C. No. 37218. S. Nos 85–748/9 L.)

INFORMATION FILED: 3–14–55, Dist. Wyo., against **Hospital Pharmacy (a partnership), Sheridan, Wyo.**

CHARGE: Between 3–30–54 and 4–7–54, *pentobarbital sodium suppositories* were dispensed once upon request for a prescription refill without authorization by the prescriber, and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–21–55. $50 fine.

4684. (F. D. C. No. 36613. S. Nos. 46–166 L, 46–168 L.)

INFORMATION FILED: 9–23–55, Dist. R. I., against **Harry Greenspan, t/a Greenspan Drug Co., Providence, R. I.**

CHARGE: On 3–3–54, *Benzedrine Sulfate tablets* were dispensed once upon a request for a prescription refill without authorization by the prescriber, and *Premarin tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–19–55. $400 fine.

4685. (F. D. C. No. 37166. S. Nos. 89–865 L, 89–887 L, 89–955/6 L.)

INFORMATION FILED: 5–13–55, Dist. Mass., against **Central Pharmacy of Revere, Inc., Revere, Mass., and Samuel Silverman (president).**

CHARGE: Between 4–7–54 and 4–20–54, *Premarin tablets* were dispensed once without a prescription, and *Benzedrine Sulfate tablets, pentobarbital sodium capsules,* and *Dexedrine Sulfate tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 8–2–55. Fine of $250 against each defendant; individual also given a 6-month suspended jail sentence and placed on probation for 1 year.

4686. (F. D. C. No. 37174. S. Nos. 89–858 L, 89–863 L, 89–889/90 L, 89–921 L.)

INFORMATION FILED: 5–13–55, Dist. Mass., against **Michaelson Drug Co., Inc., Revere, Mass., Louis Epstein (vice president and treasurer of the corporation), and Abraham Kazerman (a pharmacist).**

CHARGE: Between 4–6–54 and 4–14–54, *Premarin tablets* (count 3) and *capsules containing a mixture of apiol, ergot, aloin, and oil pennyroyal* (count 5) were each dispensed once without a prescription, and *pentobarbital sodium capsules* (counts 1 and 4) were dispensed twice and *amphetamine sulfate tablets* (count 2) were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by corporation and Epstein to all 5 counts of information and by Kazerman to counts 4 and 5.

DISPOSITION: 8–2–55. Corporation and Epstein each fined $250; Kazerman fined $100. Individuals also given 6-month suspended jail sentence and placed on probation for 1 year.

4687. (F. D. C. No. 37189. S. Nos. 89–815 L, 89–861 L, 89–874 L, 89–886 L, 89–903 L, 89–958 L.)

INFORMATION FILED: 5–13–55, Dist. Mass., against **Costanza Pharmacy (a partnership), Revere, Mass., and Charles A. Costanza and Louis Costanza (partners in the partnership).**

CHARGE: Between 3–24–54 and 4–20–54, *Premarin tablets* were dispensed once without a prescription, and *Benzedrine Sulfate tablets* were dispensed 3 times and *pentobarbital sodium capsules* and *penicillin tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by partnership to all 6 counts of information; by Charles A. Costanza to 3 counts; and by Louis Costanza to 3 counts.

DISPOSITION: 10–5–55. Partnership fined $100; each individal fined $250.

4688. (F. D. C. No. 37194. S. Nos. 89–817 L, 89–862 L, 89–909 L, 89–962 L.)

INFORMATION FILED: 5–13–55, Dist. Mass. against **Philip Berk, t/a Berk Pharmacy, Revere, Mass.**

CHARGE: Between 4–12–54 and 4–20–54, *Premarin tablets* were dispensed once without a prescription, and *pentobarbital sodium capsules, amphetamine sulfate tablets,* and *penicillin tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10–17–55. $100 fine.

4689. (F. D. C. No. 37177. S. Nos. 89–816 L, 89–856 L, 89–919/20 L, 89–959/60 L.)

INFORMATION FILED: 5–13–55, Dist. Mass., against **George V. Palladino, t/a City Hall Pharmacy, Revere, Mass., and Ralph Milano (a pharmacist).**

CHARGE: Between 4–6–54 and 4–20–54, *Ergotrate Maleate tablets, pentobarbital sodium capsules,* and *Premarin tablets* were each dispensed once without a prescription, and *penicillin tablets, pentobarbital sodium capsules,* and

Benzedrine Sulfate tablets were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by Palladino to all 6 counts of information and by Milano to 4 counts.

DISPOSITION: 9–19–55 Palladino fined $600 and Milano fined $400. Each individual also given 2-month suspended prison sentence and placed on probation for 1 year.

4690. (F. D. C. No. 37202. S. Nos. 89–813 L, 89–864 L, 89–892 L, 89–904 L, 89–953/4 L.)

INFORMATION FILED: 5–13–55, Dist. Mass., against **Crescent Pharmacy, Inc., Revere, Mass., and Bernard Greenberg and Sumner G. Paulive (pharmacists).**

CHARGE: Between 4–8–54 and 4–20–54, *Premarin tablets* (counts 1 and 6) were dispensed twice without a prescription and *amphetamine sulfate tablets* (counts 3 and 5) were dispensed twice, and *pentobarbital sodium capsules* (count 2) and *Pentids tablets* (count 4) were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by corporation to all counts of information; by Greenberg to counts 1 to 4, incl.; and by Paulive to counts 5 and 6.

DISPOSITION: 9–9–55. Corporation fined $500 and each individual fined $200.

4691. (F. D. C. No. 37232. S. Nos. 90–439 L, 90–441 L, 90–443/44 L, 90–446 L.)

INFORMATION FILED: 2–15–55, W. Dist. Mo., against **Derwood L. Piggott, t/a Piggott Drug Co., Kansas City, Mo.**

CHARGE: Between 8–5–54 and 8–9–54, *Seconal Sodium capsules* were dispensed twice, and *Dexedrine Sulfate tablets*, *Benzedrine Sulfate tablets*, and *tablets of penicillin G crystalline potassium* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–1–55. $500 fine, plus costs, and prison sentence of 1 year.

4692. (F. D. C. No. 37182. S. Nos. 67–641/5 L.)

INFORMATION FILED: 1–24–55, N. Dist. Ala., against **Reuben E. Ginn, t/a Ginn Drug Co., Birmingham, Ala., and Alexander Malcolm (a pharmacist).**

CHARGE: Between 2–19–54 and 4–16–54, *penicillin tablets* were dispensed 3 times and *Dexedrine Sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty—by each defendant.

DISPOSITION: 1–27–55. Each defendant fined $300.

4693. (F. D. C. No. 37201. S. Nos. 63–657 L, 63–670 L, 63–676 L, 63–692 L.)

INFORMATION FILED: 1–19–55, S. Dist. Ill., against **Ferd J. Noll (manager of Hohenstein's Drug Store), Bloomington, Ill.**

CHARGE: Between 5–11–54 and 6–4–54, *phenobarbital tablets*, *thyroid tablets*, *penicillin tablets*, and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–24–55. $100 fine.

4694. (F. D. C. No. 37206. S. Nos. 63–651 L, 63–666/7 L, 63–689 L.)

INFORMATION FILED: 1–10–55, S. Dist. Ill., against **Henry E. Adams, t/a Adams Drug Store, Peoria, Ill.**

CHARGE: Between 5–8–54 and 6–3–54, *penicillin tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–12–55. $500 fine, plus costs.

4695. (F. D. C. No. 35622. S. Nos. 89–378 L, 89–436/38 L.)

INFORMATION FILED: 3–24–55, E. Dist. Mo., against **Isador Kammer, t/a Belt Avenue Pharmacy, St. Louis, Mo., and Gilbert H. Noh (pharmacist).**

CHARGE: Between 7–29–54 and 8–4–54, *troches containing a mixture of penicillin G crystalline potassium and bacitracin* were dispensed once and a number of *white, gray, and pink tablets containing, among other ingredients, amphetamine sulfate, thyroid, atropine sulfate, aloin, and phenobarbital* were dispensed once without a prescription.

PLEA: Guilty—by each defendant.

DISPOSITION: 4–8–55. Kammer—$200 fine; Noh—$50 fine.

4696. (F. D. C. No. 37191. S. Nos. 84–820 L, 84–830 L, 84–912/5 L.)

INFORMATION FILED: 12–21–54, Dist. N. J., against **Meredith A. Holmes (an employee at C. Carlton Read Pharmacy), Camden, N. J.**

CHARGE: Between 5–14–54 and 6–10–54, *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 5 times and *thyroid tablets* were dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere.

DISPOSITION: 5–20–55. $250 fine and probation for 3 years.

4697. (F. D. C. No. 35135. S. Nos. 24–239 L, 37–945 L, 37–950 L, 37–952 L, 37–962/3 L.)

INFORMATION FILED: 8–20–53, Dist. N. J., against **Morris Finkelstein (a partner in the partnership of Columbian Pharmacy), East Orange, N. J.**

CHARGE: Between 10–16–52 and 10–29–52, *Seconal Sodium capsules* were dispensed twice, *dextro-amphetamine sulfate tablets* were dispensed 3 times, and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 1–15–54. $300 fine.

4698. (F. D. C. No. 37204. S. Nos. 72–792/3 L, 72–796/7 L.)

INFORMATION FILED: 1–12–55, E. Dist. Ill., against **Sweney Bros. & Co. (a partnership), Salem, Ill., and A. J. Sweney and Lee Harper Sweney (partners).**

CHARGE: Between 6–22–54 and 6–28–54, *sulfisoxazole tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–16–55. $400 fine.

4699. (F. D. C. No. 35734. S. Nos. 59–352/4 L, 59–757/8 L.)

INFORMATION FILED: 11–18–53, N. Dist. Ga., against **Thomas M. French, Sr., formerly trading as Inman Park Pharmacy, Atlanta, Ga., and Thomas M. French, Jr. (a clerk in the pharmacy).**

CHARGE: Between 6–30–53 and 7–2–53, *secobarbital sodium capsules* (counts 2 and 5) were dispensed twice and *dextro-amphetamine sulfate tablets* (count 3) and *pentobarbital sodium capsules* (count 4) were each dispensed once without a prescription, and *pentobarbital sodium capsules* (count 1) were dispensed once upon request for a prescription refill without authorization by the prescriber.

DISPOSITION: The defendants filed a motion to suppress evidence in all counts on the ground that such evidence was obtained by use of illegal entrapping measures. The motion was denied on 4–13–54. On 12–17–54, following pleas of nolo contendere by the defendants, Thomas M. French, Sr., was fined $150 and placed on probation for 2 years, and Thomas M. French, Jr., was placed on probation for 1 year.

4700. (F. D. C. No. 36622. S. Nos. 46–151 L, 46–164 L.)

INFORMATION FILED: 9–23–55, Dist. R. I., against **Anthony B. Lanfredi, t/a Bridgham Pharmacy, Providence, R. I., and John Campoli (pharmacist).**

CHARGE: Between 2–25–54 and 3–3–54, *Benzedrine Sulfate tablets* (count 1) were dispensed once upon a request for a prescription refill without authorization by the prescriber, and *Premarin tablets* (count 2) were dispensed once without a prescription.

PLEA: Guilty—by Landfredi to counts 1 and 2 and by Campoli to count 1.

DISPOSITION: 10–19–55. Landfredi—$400 fine; Campoli—$200 fine.

4701. (F. D. C. No. 37190. S. Nos. 88–482/3 L, 88–488 L, 88–492 L.)

INDICTMENT RETURNED: 3–4–55, S. Dist. Iowa, against **Clarence F. Pizinger (manager of the City Drug Store), Des Moines, Iowa, and Raymond L. Shover (a pharmacist).**

CHARGE: Between 4–4–54 and 5–6–54, *dextro-amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty—by Shover; nolo contendere—by Pizinger.

DISPOSITION: 5–11–55. Pizinger fined $1,000, plus costs; Shover fined $300.

4702. (F. D. C. No. 37192. S. Nos. 58–665 L, 65–776 L.)

INFORMATION FILED: 4–7–55, E. Dist. Mich., against **William E. Johnston and John E. Johnston (partners in the partnership of Willis Pharmacy-Johnston Brothers), Detroit, Mich.**

CHARGE: Between 3–11–54 and 3–24–54, *Dexedrine Sulfate capsules* and *Metandren Linguets* were each dispensed once without a prescription.

PLEA: Guilty—by William E. Johnston to dispensing *Dexedrine Sulfate capsules* and by John E. Johnston to dispensing *Metandren Linguets.*

DISPOSITION: 12–7–55. Each defendant fined $500.

4703. (F. D. C. No. 37186. S. Nos. 72–573 L, 72–667 L, 72–669 L.)

INFORMATION FILED: 12–27–54, W. Dist. Va., against **Robert A. Garland (partner and manager of the partnership of Garland's Drug Store), Roanoke, Va.**

CHARGE: Between 2–20–54 and 3–17–54, *dextro-amphetamine sulfate tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 5–18–55. $1,500 fine.

4704. (F. D. C. No. 37170. S. Nos. 58–087 L, 65–753/4 L, 71–391/4 L.)

INFORMATION FILED: 4–8–55, N. Dist. Ill., against **Robert P. Tomamichel (an assistant pharmacist for Walgreen Drug Store), 1941 North Western Avenue, Chicago, Ill.**

CHARGE: Between 1–21–54 and 3–10–54, *secobarbital sodium capsules* were dispensed 4 times and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 7–1–55. $70 fine, plus costs.

4705. (F. D. C. No. 37164. S. Nos. 83–463/4 L, 83–466/8 L.)

INFORMATION FILED: 12–15–54, W. Dist. Wis., against **City Drug Store (a partnership), Hurley, Wis.**

CHARGE: Between 3–2–54 and 3–9–54, *Dexedrine Sulfate tablets*, and *secobarbital sodium capsules* were each dispensed twice and *Neotresamide tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–27–55. $275 fine.

4706. (F. D. C. No. 37215. S. Nos. 57–977 L, 57–979/80 L, 75–414 L, 75–662 L.)

INFORMATION FILED: 2–4–55, Dist. Md., against **Alder Simon (secretary-treasurer and manager of King Drug Co.), Baltimore, Md., and Mary R. DeGristine (pharmacist).**

CHARGE: Between 6–1–54 and 6–16–54, *dextro-amphetamine sulfate tablets* were dispensed three times (counts 1, 2, and 3) and *sulfisoxazole tablets* were dispensed twice (counts 4 and 5) upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere—by Simon to all counts and by DeGristine to count 5.

DISPOSITION: 4–15–55. Simon—$50 fine, plus costs; DeGristine—$10 fine.

4707. (F. D. C. No. 37203. S. Nos. 59–946 L, 59–975 L, 60–356/57 L, 60–360 L.)

INFORMATION FILED: 1–26–55, N. Dist. Ga., against **Thomas R. Tyner, t/a Tyner Drug Co., Gainesville, Ga.**

CHARGE: Between 1–13–54 and 3–25–54, *penicillin G potassium tablets* and *Gantrisin tablets* were each dispensed twice and *Duozine tablets* and *Oreton-M tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–20–55. $600 fine and probation for 2 years.

4708. (F. D. C. No. 37193. S. Nos. 84–377/8 L, 84–822 L, 84–824/6 L.)

INFORMATION FILED: 2–2–55, M. Dist. Pa., against **Harry N. Arch, t/a Harry Arch Pharmacy, Harrisburg, Pa.**

CHARGE: Between 5–13–54 and 5–19–54, *capsules containing a mixture of apiol, oil tansy, powdered extract ergot, and aloin* were dispensed 3 times, and *Gantrisin tablets, Metandren Linguets,* and *thyroid tablets* were each dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 2–21–55. $500 fine and probation for 1 year.

4709. (F. D. C. No. 37175. S. Nos. 46–090 L, 46–199 L, 46–202 L, 89–788 L, 89–911 L.)

INFORMATION FILED: 6–21–55, Dist. Mass., against **Thomas P. Selleck, t/a Square Pharmacy, Taunton, Mass.**

CHARGE: Between 3–25–54 and 4–7–54, *phenobarbital tablets* were dispensed twice and *Gantrisin tablets, Benzedrine Sulfate tablets,* and *Chloromycetin capsules* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10–17–55. $400 fine.

4710. (F. D. C. No. 37196. S. No. 56050 L.)

INFORMATION FILED: 5–3–55, N. Dist. N. Y., against **John M. Bevilacqua, t/a Burleigh Pharmacy, Ticonderoga, N. Y., and Henry P. Conron (an employee).**

CHARGE: On 2–12–54, *Gantrisin tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–10–55. Bevilacqua fined $350 and Conron $150.

4711. (F. D. C. No. 35617. S. Nos. 8–001/02 M, 8–007/08 M, 8–015 M, 8–017 M.)

INFORMATION FILED: 3–28–55, W. Dist. Mo., against **Abraham I. Schnaer (a pharmacist for West Side Drugs), Kansas City, Mo.**

CHARGE: Between 11–1–54 and 11–15–54, *secobarbital sodium capsules* and *pentobarbital sodium capsules* were each dispensed twice and *penicillin G crystalline potassium tablets* and *methyltestosterone tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–1–55. $600 fine, plus costs.

4712. (F. D. C. No. 36647. S. Nos. 59–568 L, 59–570 L, 60–049 L, 60–316 L.)

INFORMATION FILED: 4–1–55, E. Dist. S. C., against **Harry N. Corontzes, t/a Evans Drug Store, Florence, S. C., and Laurie E. Suggs (a clerk).**

CHARGE: Between 11–6–53 and 12–5–53, *sulfisoxazole tablets* were dispensed twice and *penicillin G crystalline potassium tablets* and *methyltestosterone tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Corontzes to all counts of information and by Suggs to 2 counts of information involving dispensing of *sulfisoxazole tablets* and *penicillin G crystalline potassium tablets.*

DISPOSITION: 4–25–55. $200 fine against Corontzes and $100 fine against Suggs.

4713. (F. D. C. No. 37176. S. Nos. 86–297 L, 86–506 L, 86–510 L.)

INFORMATION FILED: 1–3–55, N. Dist. Ohio, against **Prospect Drug Co., Inc., Cleveland, Ohio, and Samuel Grossman (president).**

CHARGE: Between 3–16–54 and 4–1–54, *Antrenyl Bromide tablets*, *methyltestosterone tablets*, and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–28–55. Defendants fined $400 jointly.

4714. (F. D. C. No. 37178. S. Nos. 59–577 L, 60–051 L, 60–320 L.)

INFORMATION FILED: 4–1–55, E. Dist. S. C., against **Wade D. Craig, t/a Craig's Drug Store, Florence, S. C., and Marion L. Reese (a clerk at the drugstore).**

CHARGE: Between 11–9–53 and 12–5–53, *sulfisoxazole tablets*, *penicillin tablets*, and *methyltestosterone linguets* were each dispensed once without a prescription.

PLEA: Guilty—by Craig to all counts of information and by Reese to count involving dispensing of *penicillin tablets*.

DISPOSITION: 4–25–55. Craig fined $200 and Reese $50.

4715. (F. D. C. No. 37179. S. Nos. 59–799/800 L, 59–950 L, 59–971 L.)

INFORMATION FILED: 1–11–55, M. Dist. Ga., against **Rufus D. Allen (manager and pharmacist for Hogg's Drug Store), 3145 Napier Avenue, Macon, Ga., and Carles H. Brooks (pharmacist).**

CHARGE: Between 11–11–53 and 3–1–54, *methantheline bromide tablets*, *thyroid tablets*, *methyltestosterone tablets*, and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Allen to dispensing *methantheline bromide tablets* and *dextro-amphetamine sulfate tablets* and by Brooks to dispensing the other drugs involved.

DISPOSITION: 3–2–55. Each defendant fined $50.

4716. (F. D. C. No. 37167. S. Nos. 85–653 L, 85–667 L, 85–671 L, 85–698 L.)

INFORMATION FILED: 12–27–54, Dist. Colo., against **William H. Robinson, t/a Economy Drug Co., Grand Junction, Colo.**

CHARGE: Between 2–8–54 and 3–22–54, *methyltestosterone tablets* were dispensed once without a prescription, and *dextro-amphetamine sulfate tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10–21–55. $1,000 fine.

4717. (F. D. C. No. 36624. S. No. 86–232 L.)

INFORMATION FILED: 11–1–54, S. Dist. Ind., against **Edward G. Walz, t/a Walz Pharmacy, New Harmony, Ind.**

CHARGE: On 1–26–54, *methyltestosterone tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–2–55. $200 fine, plus costs.

4718. (F. D. C. No. 35830. S. No. 70–880 L.)

INFORMATION FILED: 5–25–54, S. Dist. Ind., against **Cassius L. Schafer (a pharmacist for Joseph F. Schafer Drug Store), Poseyville, Ind.**

CHARGE: On 12–9–53, a quantity of *chloral hydrate compound* was dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–25–54. $300 fine, plus costs.

4719. (F. D. C. No. 37205. S. Nos. 63–662/4 L, 63–685/6 L.)

INFORMATION FILED: 1–10–55, S. Dist. Ill., against **Dale H. Bricker, t/a Border's Drug Store, Peoria, Ill.**

CHARGE: Between 5–18–54 and 6–2–54, *thyroid tablets, capsules containing a mixture of secobarbital sodium and amobarbital sodium,* and *tablets containing a mixture of sulfadiazine, sulfathiazole, and sulfamerazine* were each dispensed once without a prescription, and *sulfisoxazole tablets* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 1–12–55. $500 fine, plus costs.

4720. (F. D. C. No. 36669. S. No. 64–281 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against **Billy C. Nelson (a pharmacist for Vista Pharmacy), Spenard, Alaska.**

CHARGE: On 8–28–53, *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–24–55. $50 fine.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4721–4740

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced or delivered for introduction into, or while in, interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which default or consent decrees of condemnation were entered and (2) criminal proceedings which were terminated upon pleas of nolo contendere or guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms or individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 18, 1956.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see No. 4727; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4727; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4727; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 4725.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4721–4740

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality and purity fell below the standard set forth in such compendium; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (c), certain information required by the Act to appear on the label of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (g), the article purported to be a drug the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not packaged as prescribed therein; Section 502 (j), the article was dangerons to health when used in the dosage, and with the frequency and duration prescribed, recommended, or suggested in its labeling; and, Section 503 (b) (4), the article in one case was subject to Section 503 (b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," and in another case the label of the article bore the caution statement as quoted above, but the article was not one to which Section 503 (b) (1) applies.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4721. Vaginal suppositories (3 seizure actions). (F. D. C. Nos. 37610, 37617, 37675. S. Nos. 1–234/5 M, 6–931 M, 14–246 M.)

QUANTITY: 187 boxes at Denver, Colo., St. Louis, Mo., and Miami, Fla.

SHIPPED: Between 8–3–54 and 11–26–54, from Cleveland, Ohio, by Williams Mfg. Co.

LABEL IN PART: (BOX) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum–Borax–Petrolatum Prepared by Dr. J. A. McGill Co., Not Inc. 2001–3 Indiana Ave., Chicago 16, Ill."

ACCOMPANYING LABELING: Leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

RESULTS OF INVESTIGATION: Examination showed that the article contained between 44 percent and 50 percent ammonium alum.

LIBELED: Between 1–21–55 and 2–21–55, Dist. Colo., E. Dist. Mo., and S. Dist. Fla.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective

treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: Between 2–21–55 and 3–25–55. Default—destruction.

4722. Vaginal suppositories. (F. D. C. No. 37643. S. No. 6–180 M.)

QUANTITY: 35 boxes at Terre Haute, Ind.

SHIPPED: 10–8–54, from Cleveland, Ohio, by Williams Mfg. Co.

LABEL IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum – Borax – Petrolatum Prepared by Dr. J. A. McGill Co., Not Inc. 2001–3 Indiana Ave., Chicago 16, Ill."

ACCOMPANYING LABELING: Leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

RESULTS OF INVESTIGATION: Examination showed that the suppositories each weighed approximately 5.3 grams and contained approximately 47 percent ammonium alum.

LIBELED: On or about 2–15–55, S. Dist. Ind.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: 3–18–55. Default—destruction.

4723. Vaginal suppositories. (F. D. C. No. 37916. S. Nos. 14–958 M, 15–240 M.)

QUANTITY: 17 boxes at Fresno, Calif.

SHIPPED: Between 8–24–54 and 12–19–54, from Chicago, Ill., by Dr. J. A. McGill Co.

LABEL IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum – Borax – Petrolatum Prepared by Dr. J. A. McGill Co. * * * Chicago 40, Ill."

ACCOMPANYING LABELING: Leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

RESULTS OF INVESTIGATION: Examination showed that the suppositories each weighed approximately 5.2 grams and contained approximately 50 percent ammonium alum.

LIBELED: 4–1–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: 4–29–55. Default—destruction.

4724. Vaginal suppositories. (F. D. C. No. 37501. S. No. 15–081 M.)

QUANTITY: 14 boxes, 6 suppositories each, at Sacramento, Calif.

SHIPPED: 10–14–54, from Cleveland, Ohio, by Williams Mfg. Co.

LABEL IN PART: (Box) "Orange Blossom Suppositories * * * Alum – Borax – Petrolatum * * * Prepared by Dr. J. A. McGill Co., Not Inc., 2001–3 Indiana Ave., Chicago 16, Ill."

ACCOMPANYING LABELING: Leaflets entitled "Dr. J. A. McGill Co.'s Suppositories."

LIBELED: 12–13–54, N. Dist. Calif.

CHARGE: 502 (a)—the label statements "For Simple Irritations of The Vaginal Tract" were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: 3–3–55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4725. Terramycin capsules. (F. D. C. No. 37604. S. No. 11–380 M.)

QUANTITY: 538 16-capsule btls. at Houston, Tex.

SHIPPED: Prior to 1–23–53, from New York, N. Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Btl.) "Pfizer Terramicina Clorhidrato Cristalina Frasco De 16 Capsulas * * * Formula: Cada capsula contiene Clohidrato de Terramicina Cristalina Equivalente a: 0.250 g. de Terramicina Cristalina Anfoterica Pura Fabricado por Chas. Pfizer & Co., Inc. Nueva York * * * Control No. WLP 527747."

LIBELED: 2–23–55, S. Dist. Tex.

CHARGE: 502 (c)—the information required by 502 (b) and 502 (e) to appear on the label of the article was not placed thereon, when shipped, in such terms

as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since the label was printed entirely in the Spanish language; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement; and 503 (b) (4)—the article was subject to 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6–16–55. Default—destruction.

4726. Ovary powder. (F. D. C. No. 37634. S. No. 12–290 M.)

QUANTITY: 1 drum containing 1 lb., 6 4-oz. jars, and 2 1-lb. jars at Jersey City, N. J.

SHIPPED: 12–22–54, from New York, N. Y., by Desmo Chemical Corp.

LABEL IN PART: (Drum) "Net: 5 lbs. * * * Ovarian Substance Powder N. F."; (jar) "Ovary Powder N. F. * * * Scientific investigation has not demonstrated the presence of therapeutically useful constituents in this product * * * Caution: Federal law prohibits dispensing without prescription.

RESULTS OF INVESTIGATION: The article in the jars was repacked by the consignee from the bulk drum.

LIBELED: 2–1–55, Dist. N. J.

CHARGE: 502 (a)—the labeling of the article (in bulk and as repacked), when shipped and while held for sale, contained false and misleading representations that the article was recognized in the National Formulary, an official compendium; 502 (f) (1)—the labeling of the article (in bulk and as repacked), when shipped and while held for sale, failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement; and 503 (b) (4)—the label of the article (as repacked), while held for sale, bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not one to which 503 (b) (1) applies.

DISPOSITION: 6–30–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4727. Liquid herbal drugs. (F. D. C. No. 35576. S. Nos. 53–354/5 L, 53–460 L, 53–870 L, 63–141 L, 63–150 L, 63–314/5 L, 63–711/3 L.)

INDICTMENT RETURNED: 10–25–54, W. Dist. Ky., against Ples Griffin, La Center, Ky.

SHIPPED: Between 11–18–53 and 12–20–53, from Kentucky to Illinois, Missouri, and Tennessee.

CHARGE: 502 (b)—when shipped, the drugs failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502 (e) (2)—the labels of the drugs failed to bear the common or usual name of each active ingredient; and 502 (f) (1)—the labeling of the drugs failed to bear adequate directions for use in the treatment of the diseases, symptoms, conditions, and purposes for which the drugs were prescribed, recommended, and suggested orally by the defendant, and in the cases of some drugs, the labeling failed also to reveal the conditions for which such drugs were to be used.

*See also Nos. 4725, 4726.

PLEA: Guilty.

DISPOSITION: 6–13–55. $1,000 fine plus costs, sentence of 18 months in jail suspended, and probation for 3 years.

4728. **Water-soluble extract of anterior pituitary substance.** (F. D. C. No. 37085. S. No. 83–984 L.)

QUANTITY: 111 cartons, 1 vial each, at St. Paul, Minn.

SHIPPED: 11–12–52, from Birmingham, Ala., by Veltex Co.

LABEL IN PART: (Vial) "10 cc. Multiple Dose Vial Water Soluble Extract of Anterior Pituitary Substance * * * Chlorobutanol 0.5% * * * Dist. by Farmers Veterinary Supply Co. St. Paul 1, Minn. Each cc. contains 10 mgs. of water soluble, heat stable extract derived from 0.75 gms. of fresh anterior pituitary substance * * * Note: No claims are made for anterior pituitary hormone activity. Caution: Federal law prohibits dispensing without a prescription. For Veterinary Use Only."

LIBELED: 9–10–54, Dist. Minn.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 11–3–54. Default—destruction.

4729. **Vic-To-Ry oil.** (F. D. C. No. 37923. S. No. 8–734 M.)

QUANTITY: 18 4-oz. btls. and 20 16-oz. btls. at Broken Bow, Nebr.

SHIPPED: 3–7–55, from Burlington, Kans., by Mrs. Sarah F. Harreld.

LABEL IN PART: (Btl.) "Mother Harreld's Vic-To-Ry Oil * * * Active Ingredients: Turpentine, Kerosene and camphor gum combined with oil base Manufactured by S. F. Harreld R. F. D. 2, LeRoy, Kansas."

ACCOMPANYING LABELING: A circular entitled "Directions for Mother Harreld's Vic-To-Roy Oil."

LIBELED: 4–18–55, Dist. Nebr.

CHARGE: 502 (a)—the labeling of the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for cuts, burns, bruises, all forms of rheumatism, head and chest colds, corns, callouses, bunions, pneumonia, piles, arthritis, cataract, hardening of the arteries, stiff sore joints, and all muscular ailments; and 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 5–11–55. Consent—destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4730. **Dried herbs.** (F. D. C. No. 36575. S. Nos. 58–274 L, 58–896 L.)

INFORMATION FILED: 8–9–54, N. Dist. Ill., against Z. G. Stanis Co., a partnership, Chicago, Ill.

ALLEGED VIOLATION: Between 1947 and 11–19–53, the defendant, while holding a number of bags of Seventeana tea for sale after shipment in interstate commerce, caused such article to be held in a building accessible to insects and to be exposed to contamination by insects; caused a quantity of the article to be repacked into boxes under the designation "Z–G Herbs" and to be accompanied by a leaflet; and caused a number of boxes of the article accompanied by the

leaflet to be introduced into interstate commerce for delivery to Milwaukee, Wis.

LABEL IN PART: (Bag) "102 Lbs. Seventeana Tea"; (box) "Z–G Herbs Net Weight 4 Oz. No. 17 Herb Tea."

ACCOMPANYING LABELING: Leaflet entitled "Temporary List of Z. G. Herbs and Stanis Products."

CHARGE: 501 (a) (1)—contained insects and insect parts while held for sale and when shipped by the defendant as described above; 501 (a) (2)—held under insanitary conditions; and 502 (a)—the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for stomach disorders.

PLEA: Nolo contendere.

DISPOSITION: 3–8–55. $400 fine, plus costs.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4731. Powdered extract veratrum viride. (F. D. C. No. 34912. S. No. 38–064 L.)

QUANTITY: 1 20-lb. drum at Brooklyn, N. Y.

SHIPPED: 10–18–52, from North Bergen, N. J., by Meer Corp.

LABEL IN PART: (Drum) "Powdered Extract Veratrum Viride Poison Each 100 grams of extract contains 5 grams of the total alkaloids of Veratrum Viride."

RESULTS OF INVESTIGATION: Examination showed that the article contained less than the declared amount of total alkaloids of veratrum viride.

LIBELED: 3–26–53, E. Dist. N. Y.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each 100 grams of extract contains 5 grams of the total alkaloids of Veratrum Viride" was false and misleading.

DISPOSITION: 7–1–55. Consent—destruction.

4732. Cough syrup. (F. D. C. No. 37889. S. No. 12–571 M.)

INFORMATION FILED: 7–25–55, E. Dist. N. Y., against Ormont Drug & Chemical Co., Inc., Long Island City, N. Y., and Henry L. Spiro, president.

SHIPPED: 8–6–54, from New York to New Jersey.

LABEL IN PART: (Btl.) "Codamin Cough Syrup * * * Prepared for Center Pharmacy Fort Lee, N. J."

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported and was represented to possess in that 1 teaspoonful (5 cc.) of the article purported and was represented to contain 10.0 milligrams of pyrilamine maleate, whereas 1 teaspoonful (5 cc.) of the article contained less than 10.0 milligrams of pyrilamine maleate.

PLEA: Guilty.

DISPOSITION: 10–6–55. Corporation fined $750 and individual $500.

4733. Adhesive bandages. (F. D. C. No. 37607. S. No. 12–589 M.)

QUANTITY: 696 boxes at Perth Amboy, N. J.

SHIPPED: 11–4–54, from New Rochelle, N. Y., by Hampton Mfg. Co.

LABEL IN PART: (Box) "10 ¾" x 3" Blue Cross Plastic Adhesive Bandages Sterile * * * Waterproof * * * 'Mercurochrome' Pads."

LIBELED: On or about 1–24–55, Dist. N. J.

CHARGE: 501 (b)—the quality and purity of the article when shipped fell below the standard for "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]" set forth in the United States Pharmacopeia since the article was not sterile but was contaminated with living micro-organisms; and 502 (a)—the label statement "Sterile" was false and misleading.

DISPOSITION: 2–28–55. Default—destruction.

4734. Rubber prophylactics. (F. D. C. No. 36556. S. No. 38–399 L.)

QUANTITY: 5 gross at New York, N. Y.

SHIPPED: 11–28–49, from Japan.

RESULTS OF INVESTIGATION: Examination of 25 devices showed that 11, or 44 percent, were defective in that they contained holes.

LIBELED: 4–19–54, S. Dist. N. Y.

CHARGE: 501 (c)—the quality of the article while in interstate commerce fell below that which it purported and was represented to possess.

DISPOSITION: 8–29–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4735. Adler's Compound. (F. D. C. No. 36646. S. No. 64–741 L.)

INDICTMENT RETURNED: 1–12–55, S. Dist. Calif., against Wayne Parkinson, t/a Glandular Products Co.; Sleep-Eze Co., Inc., t/a Tide Mailing Service; and Allen H. Parkinson, president of Sleep-Eze Co., Inc., all of Long Beach, Calif.

ALLEGED VIOLATION: The indictment alleged that the defendants, on 2–15–54, caused the introduction into interstate commerce, for delivery to Seattle, Washington, of the drug which was misbranded as described below. The indictment further alleged that Allen H. Parkinson did such act with intent to defraud and mislead.

LABEL IN PART: "Adler's [Picture of a man] Compound Standard Strength Contents 60 Tablets Distributed by Glandular Products Company Long Beach, California U. S. A. Each Tablet Contains: Potassium (Sulfate) 1.5 mg. Vitamin B–1 1.5 mg. Vitamin C 5.0 mg. Niacinamide 5.0 mg. Caffein 0.5 gr. Molybdenum (Sodium Molybdenate) 0.2 mg. Calcium Pantothenate 2.5 mg. Vitamin B–12 1.5 mcg."

ACCOMPANYING LABELING: An undated letter addressed to "Dear Sir," bearing the letterhead "Konrad Adler & Company Fachleute auf dem Gebiete der Drusenforschung Stuttgarterstrassen 18–20 Frankfurt am Main Germany Bank Reference Rhein-Main-Bank Frankfurt am Main," and signed "Konrad Adler"; a leaflet bearing the heading "Konrad Adler & Company Sole Licensors of Adler's Compound"; an "Order Form"; an air mail business reply envelope addressed to Glandular Products Company; and an envelope bearing the return address "Konrad Adler & Company Frankfurt am Main, Germany," the postmark "London, S. E. I.," and English postage stamps.

*See also Nos. 4721–4724, 4726, 4729–4731, 4733.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for male sexual weakness; that it was a new and amazing medical miracle and was a new, original, and secret German formula; that the tablets comprising *Adler's Compound, Super Strength*, possessed twice the potency of the tablets comprising *Adler's Compound, Standard Strength*, when in fact they possessed the same potency; that the article was manufactured in Germany and was available in the United States in limited supply only; that Konrad Adler and Konrad Adler & Co. were doing business in Stuttgarterstrassen 18–20, Frankfurt am Main, Germany, and were maintaining advertising and sales offices at 4 Berkley Street, London, England; and that the person whose picture appeared in the aforementioned labeling was Konrad Adler, a German specialist in glandular research.

PLEA: Nolo contendere.

DISPOSITION: 10–17–55. Wayne Parkinson—placed on probation for 5 years; Sleep-Eze Co., Inc.—fined $500; Allen H. Parkinson—fined $500, sentenced to prison for 1 year (suspended), and placed on probation for 5 years.

4736. Vita-Glan male formula. (F. D. C. No. 35560. S. Nos. 2–675 L, 2–743 L.)

INFORMATION FILED: 10–15–53, S. Dist. Calif., against Wayne Parkinson, t/a Glandular Products Co., and as Dybutol Co., Long Beach, Calif.

SHIPPED: 12–31–52 and 1–22–53, from California to Georgia and Florida.

LABEL IN PART: (Btl.) "Vita-Glan Male Formula * * * Sole Distributors Glandular Products Co. Long Beach, California Each Tablet Contains Vitamin B–1 5 Mg. 500% MDR* Vitamin B–2 3.5 Mg. 175% MDR* Niacinamide 15 Mg.** In a base of Orchic, Pancreatin, Prostate and Adrenal Gland Substances, plus other excipients. The gland substances in Vita-Glan are inert and absolutely safe.

*Minimum Daily Adult Requirements.

**Need But Requirements Not Established."

ACCOMPANYING LABELING: Leaflet entitled "Amazing New Vita-Glan 4 Gland Substances Are Now Found In Vita-Glan."

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the drug contained physiologically active glandular substances; that the glandular constituents were of value in overcoming glandular deficiencies in the human male; and that the article would be an adequate and effective treatment for male sexual weakness, nervousness, loss of muscle tone, aches and pains, fatigue, irritability, headaches, dizziness, weakness, mental depression, insomnia, digestive upsets, loss of appetite, neuritis, backache, mental dullness, and for enabling men past 40 to have the sexual vitality of a younger man.

PLEA: Nolo contendere.

DISPOSITION: 10–17–55. $250 fine and probation for 5 years.

4737. C-Tone. (F. D. C. No. 36609. S. Nos. 17–640 L, 17–642 L, 17–646 L.)

INFORMATION FILED: 10–19–54, Dist. N. J., against Byrne Products, Inc., New York, N. Y., and Thomas F. Byrne, president of the corporation.

SHIPPED: 6–26–53 and 7–17–53, from New Jersey to California.

LABEL IN PART: (Btl.) "Rich in Activated Enzymes C-Tone The *Natural* Vitamin C Tonic * * * 8 Fl. Oz. Net Sole and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

ACCOMPANYING LABELING: Leaflets entitled "Which of These Dread Killers Threaten Your Advancing Years?"; display placards reading, in part, "Which of These Conditions Threaten Your Advancing Years?"; "Natural C-Tone For That * * * Pep of Health! For That * * * Vigorous Feeling!"

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article would be of nutritional and therapeutic value because of its enzyme content and would be effective as a tonic; that it would be an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells; and that it would be effective to provide energy and improve digestion.

PLEA: Corporation—guilty to counts 1 and 2; individual—nolo contendere to count 1 relating to shipment of 6–26–53.

DISPOSITION: 6–3–55. Corporation fined $400 and individual $100.

4738. Alfacene. (F. D. C. No. 36094. S. No. 59–308 L.)

QUANTITY: 4 cartons, 12 8-oz. btls. each, at Charlotte, N. C.

SHIPPED: 9–12–53, from New Castle, Va., by Alfacene Co.

LABEL IN PART: (Btl.) "This excellent preparation made from the highest Quality Alfalfa Seed obtainable. Alfacene."

ACCOMPANYING LABELING: Circulars designated "Are You Suffering From Arthritis Or Rheumatism?"

RESULTS OF INVESTIGATION: The above-mentioned circulars were printed locally for the consignee, the Interstate Sales & Distributing Co.

LIBELED: Between 10–28–53 and 11–9–53, W. Dist. N. C.

CHARGE: 502 (a)—the labeling of the article when shipped and while held for sale contained false and misleading representations that the article was an adequate and effective treatment for arthritis and rheumatism.

DISPOSITION: 12–17–53. Default—destruction.

4739. Electreat (device). (F. D. C. No. 37513. S. No. 16–087 M.)

QUANTITY: 6 retail cartons containing 1 device each, at College Place, Wash., in the possession of L. W. MacArthur, the consignee.

SHIPPED: 10–29–54, from Peoria, Ill., by Electreat Mfg. Co.

ACCOMPANYING LABELING: Pamphlet and leaflets entitled "Electreat Massage" and mimeographed circulars entitled "Library Chart."

RESULTS OF INVESTIGATION: The device was an elongated metallic cylinder housing an induction coil with a make-and-break current switch, operated by two "flash-light" batteries. The cylinder had a smaller roller attachment at one end. When in operation, the device would give off an interrupted-type electrical current at a high voltage but of very low intensity.

The above-mentioned pamphlet and leaflets were included in the shipping carton containing the device, and the circulars were prepared by the consignee and used in selling the device.

LIBELED: 12–8–54, E. Dist. Wash.

CHARGE: 502 (a)—the labeling accompanying the article when shipped and while held for sale contained false and misleading representations that the

device was effective for preserving and restoring harmony of action between different organs and parts of the body; treating conditions affecting the heart, lungs, stomach, liver, adrenals, kidneys, bowels, vertebras, ear, nose, teeth, eyes, tonsils, thyroid, throat, bladder, ovaries, genitalia, rectum, and spinal column; and treating coughs, impaired circulation, impure blood, prostate conditions, sinus conditions, headache, sciatica, lumbago, and pleurisk.

DISPOSITION: 2–15–55. Default—delivered to the Food and Drug Administration.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

4740. Water for injection. (F. D. C. No. 37918. S. No. 4–692 M.)

QUANTITY: 494 vials at Buffalo, N. Y.

SHIPPED: 7–23–53, from Philadelphia, Pa., by Addison Laboratories.

LABEL IN PART: (Vial) "100 cc. Multiple Dose Vial Water for Injection * * * Contains No Bacteriostatic Agent."

RESULTS OF INVESTIGATION: Each vial was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus, the contents of the vial could be withdrawn without removal or destruction of the closure.

LIBELED: 4–6–55, W. Dist. N. Y.

CHARGE: 502 (g)—the article was a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, it was not packaged as prescribed therein.

DISPOSITION: 5–10–55. Default—destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1956

D. D. N. J., F. D. C. 4741–4760 Issued September 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4741–4760

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation; (2) criminal proceedings which were terminated upon pleas of guilty or nolo contendere; (3) injunction proceedings terminated with the entry of injunctions; and (4) contempt proceedings for violation of an injunction which were terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal, injunction, and contempt proceedings are against the *firms or individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *August 30, 1956.*

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*For violative sales of prescription drugs, see No. 4742; presence of a habit-forming narcotic without warning statement, Nos. 4747–4759; omission of, or unsatisfactory, ingredients statements, Nos. 4743, 4745; sale under name of another drug, No. 4755; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4745, 4747–4749; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4744, 4745.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4741–4760

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2), an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (i) (3), the article was offered for sale under the name of another drug; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of a kind of chlortetracycline or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (1), the article was dispensed without a prescription therefor from a practitioner licensed by law to administer the article; section 503 (b) (4), the article in several cases was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," and, in another case, the label of the article bore the caution statement as quoted above, but the article was not one to which Section 503 (b) (1) applies.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4741. Vaginal suppositories. (Inj. No. 281.)

COMPLAINT FOR INJUNCTION FILED: 9–1–54, N. Dist. Ind., against Grayce, Inc., South Bend, Ind., and Juanita E. Feather, secretary-treasurer, to enjoin the interstate shipment of the above-mentioned article.

LABEL IN PART: (BOX) "OAK BALM VAGINAL SUPPOSITORIES FOR FEMININE HYGIENE Each Suppository contains: Ichthammol Boric Alum Potassium Golden Seal Root in a Cocoa Butter Base. Distributed by GRAYCE, INC. (Sole Distributors) South Bend, Indiana."

ACCOMPANYING LABELING: A circular entitled "Oak Balm Works Wonders for Women" and a mimeographed sheet entitled "Doctors' Price List."

CHARGE: The complaint alleged that the article, when used as a suppository

in the vagina in the manner recommended in its labeling, was unsafe and dangerous to health since the article, because of its alum content, might cause serious injury by destroying normal, healthy tissue in the vaginal tract; and, that the defendants had been and still were introducing into interstate commerce such article which was misbranded under 502 (a) in that its labeling created the false and misleading impression that the article was a safe, adequate, and effective treatment for minor irritations of the mucous membranes of the vaginal tract, and which also was misbranded under 502 (j) in that the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling.

The complaint alleged further that if the defendants were forced by an injunction to refrain from using the existing labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article in interstate commerce without labeling stating the dosage of the article and without labeling stating the conditions and purposes for which the article was intended; and that, in such case, the article would be misbranded under 502 (f) (1) in that its labeling would fail to bear adequate directions for use because of the omission from its labeling of the dosage of the article and of statements of the conditions and purposes for which the article was intended.

DISPOSITION: The matter came on for hearing on the issuance of a preliminary injunction on 10–21–54. The application for a preliminary injunction was denied on 11–15–54, at which time the case came on for trial before the court on the issue of granting a permanent injunction. On 12–4–54, the court entered a decree permanently enjoining the defendants from introducing into interstate commerce the above-named article of drug misbranded under 502 (a), 502 (f) (1), or 502 (j), and handing down the following opinion, findings of fact, and conclusions of law:

PARKINSON, *District Judge:* "This is an injunction proceeding under the Federal Food, Drug and Cosmetic Act which was tried to the Court first on an order to the defendants to show cause why a preliminary injunction should not issue and a few days later on the question of whether or not a permanent injunction should issue.

"Upon submission on the order to show cause, the Court reserved its ruling thereon until trial on permanent injunction and, by agreement of the parties, fixed a trial date therefor.

"The cause was submitted to the Court for trial on the date fixed and it is a decision of the cause on the merits which now solicits the attention of this Court.

"The Federal Food, Drug and Cosmetic Act was designed to protect the public, the vast multitude which includes the ignorant, the credulous and the unthinking who, when making a purchase, do not stop to analyze. As a whole its primary purpose is to protect consumers from dangerous products which come within the purview thereof.

"The Act provides inter alia, that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular or if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, and prohibits the introduction into interstate commerce of a misbranded drug.

"The pleadings admit and the undisputed evidence is that the defendants have been and still were at the time of trial, distributing in interstate commerce Oak Balm Vaginal Suppositories prepared from the following formula:

Alum	10 lbs.
Cocoa Butter	9 lbs.
Borax	6 lbs.
Golden Seal Powder	2½ lbs.
Ichthammol	2¼ lbs.
Olive Oil	1 qt.

for use in the treatment of temporary minor vaginal irritations accompanied by a label so stating and prescribing directions therefor.

"The proof is convincing that the drug is misbranded because its labeling is false and misleading in that it has no therapeutic value whatsoever and instead of being efficacious in the cure of minor vaginal irritations is in fact harmful and will produce vaginal irritations instead of remove them; that its use could produce an ulcer and when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling is dangerous to health.

"The label which accompanies the suppositories states that the suppositories are to be used for temporary minor vaginal irritations and directs that a suppository be inserted into the vagina as high as possible and SO LONG AS NO IRRITATION RESULTS do not disturb for three days and nights. In other words, the defendants contemplate that the suppositories may cause the very condition they are placed on the market and sold to the public by the defendants to remedy. Because of the labeling and of the strong astringent properties of the suppository, all as shown by the evidence, this Court is of the opinion that the defendants are implicitly holding out to the public and selling Oak Balm Vaginal Suppositories for a use other than that set forth in the label.

"Therefore, the Court having considered all of the evidence adduced, the arguments of counsel and the law applicable thereto does now make the following

FINDINGS OF FACT

1.

"The defendant, Grayce, Inc., is an Indiana Corporation doing business at 757 Lincolnway East, South Bend, Indiana, and the defendant, Juanita E. Feather, is the Secretary-Treasurer thereof and is the person actively engaged in the operation of the business of the defendant, Grayce, Inc.

2.

"Since October 1950, the defendant, Grayce, Inc., has been engaged in the business of selling and distributing drugs in interstate commerce including a drug marketed as Oak Balm Vaginal Suppositories which is prepared from the following formula:

Alum	10 lbs.
Cocoa Butter	9 lbs.
Borax	6 lbs.
Golden Seal Powder	2½ lbs.
Ichthammol	2¼ lbs.
Olive Oil	1 qt.

and continually represented by the defendants as a safe and effective treatment for temporary minor vaginal irritations.

3.

"Said Oak Balm Vaginal Suppositories are articles intended for use in the treatment, mitigation or cure of disease in women and are a drug.

4.

"Said drug has no therapeutic value and instead of being efficacious in the cure of minor vaginal irritations is harmful and the labeling thereof by the defendants is false and misleading and said drug is misbranded.

5.

"The use of said drug in accordance with the directions on the label will cause mucous membrane of the vaginal tract which is already irritated to become worse, and will cause healthy tissue to become irritated, and the irritation caused by its use would range from slight damage by the use of a single suppository to severe ulceration with continued use.

6.

"The use of said drug will not benefit any irritation of the vaginal tract but will produce irritation to the mucous membrane of the vaginal tract and when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof is dangerous to health.

7.

"The defendants have continued to distribute said Oak Balm Vaginal Suppositories in interstate commerce despite warnings that the drug was and is misbranded, and are now engaged in the introduction, sale, delivery for introduction and distribution in interstate commerce of said misbranded drug and will, unless enjoined, continue so to do.

"Upon the foregoing special findings of fact, the Court now does state its

CONCLUSIONS OF LAW

1.

"This Court has jurisdiction of the parties to and the subject matter of the action.

2.

"Oak Balm Vaginal Suppositories are a drug within the meaning of 21 U. S. C. 321 (g) (2) because they are intended for use in the cure, mitigation, and treatment of diseases of the vagina.

3.

"Oak Balm Vaginal Suppositories have been and are misbranded within the meaning of 21 U. S. C. 352 (a) because the statements contained in the labeling that the drug is a safe and effective treatment for minor irritations of the vaginal tract are false and misleading.

4.

"Oak Balm Vaginal Suppositories have been and are misbranded within the meaning of 21 U. S. C. 352 (j) because when used as recommended in the labeling, in the dosage and for the duration prescribed, the drug is dangerous to the health of the user.

5.

"By introducing this misbranded drug into interstate commerce, the defendants have, over a period of years, been violating the provisions of 21 U. S. C. 331 (a).

6.

"The drug involved would be misbranded within the meaning of 21 U. S. C. 352 (f) (1) were the defendants as a result of an injunction to introduce the drug in interstate commerce without labeling stating the disease conditions for which it is intended to be used, since 21 U. S. C. 352 (f) (1) requires that the labeling state adequate directions for use, which include directions as to the conditions in which the drug is to be used.

7.

"The United States of America, plaintiff, is entitled to a permanent injunction restraining the defendants, their officers, agents, servants, employees, and representatives, and all those persons in active concert or participation with them from introducing or causing to be introduced, or delivering, or causing to be delivered for introduction into interstate commerce Oak Balm Vaginal Suppositories or any drug having the same or similar composition which is misbranded with the meaning of 21 U. S. C. 352 (a), 352 (f) (1) and 352 (j).

"IT IS THEREFORE ORDERED, ADJUDGED AND DECREED as follows:

"(1) That the Court has jurisdiction of the subject matter herein and of all persons or parties hereto and the complaint states a cause of action against the defendants under the Federal Food, Drug, and Cosmetic Act;

"(2) That the defendants, Grayce, Inc., an Indiana corporation and Juanita E. Feather, an individual, and each and all of their agents, servants, employees and representatives, and all and any persons in active concert or participation with them or any of them who receive actual notice of this decree by personal service or otherwise, be and they are hereby perpetually enjoined and restrained under the provisions of 21 U. S. C. 332 (a) from directly or indirectly introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, in violation of Section 301 (a) of the

Act (21 U. S. C. 331 (a)), the article of drug labeled in part 'Oak Balm Vaginal Suppositories' or any other article of drug of similar composition which is:

(a) misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any representation or suggestion in the labeling of such article that such article is a safe, adequate and effective treatment for minor irritations of the vaginal tract or by reason of any other false and misleading representations or suggestions in the labeling of such article; or

(b) misbranded within the meaning of Section 502 (f) (1) of the Act (21 U. S. C. 352 (f) (1)) because the labeling of such article fails to state the dosage for such article or all the conditions and purposes for which such article is intended; or

(c) misbranded within the meaning of Section 502 (j) of the Act (21 U. S. C. 352 (j)) because such article is recommended for use in the vaginal tract.

"(3) That the defendants, Grayce, Inc., an Indiana corporation, and Juanita E. Feather, an individual, shall give written notice of the provisions of this decree to each and all of their present and future agents, servants, employees and representatives, and all persons now or in the future in active concert or participation with them who assist in the manufacture, preparation and distribution of said article of drug or any similar article of drug.

"(4) That jurisdiction of this Court is retained for the purpose of enforcing or modifying this decree and for the purpose of granting such additional relief as may hereinafter appear necessary or appropriate.

"That the plaintiff, the United States of America, have and recover from the defendants the costs of this action, as taxed herein, to-wit, the sum of $_____, and that the plaintiff have execution thereof.

"The question on the order to show cause why a preliminary injunction should not issue being now moot, the defendants should be discharged therefrom, and IT IS SO ORDERED."

The defendants filed a motion for a new trial on 12–14–54. The court denied their motion on 3–18–55, handing down the following opinion:

PARKINSON, *District Judge:* "The Court at the time of the trial of this cause following the evidence very closely, and subsequent to the filing of the motion for a new trial by the defendants, the Court has had the benefit of the transcript of the entire proceedings, including all of the evidence, and has had the opportunity to make a very careful and complete review of all of the evidence and all of the rulings of the Court thereon during the trial of this cause.

"When we come to a consideration of the motion for a new trial, and we take each of the specifications up one by one, number 1 is that, 'The Court in its opinion filed on to-wit: December 4, 1954, based its findings on evidence erroneously admitted in the record over the objections of the defendants,' the Court finds no such situation to exist, and certainly, in the opinion of the Court, the special findings and conclusions were all based on evidence that was not erroneously admitted.

"2. 'The Court erred in admitting into evidence as exhibits certain documents offered by the Food, Drug and Cosmetics Administration, no foundation for the admission of said documents having been established.' There were no exhibits offered by the Food, Drug and Cosmetics Administration in this case. There were exhibits offered by the plaintiff, the United States of America, but not by the Food, Drug and Cosmetics Administration, and even if the Court were to consider that specification on the basis that any question was properly raised, there would be no merit therein.

"3. 'The Court erred in admitting the testimony of Dr. Y. T. Oster over the objection of the defendants.' When we consider the testimony of Dr. Oster, the transcript shows this evidence was admitted without objection on the part of the defendants. He testified that he had a Bachelor of Science degree in pharmacy from the University of Notre Dame; an M. S. degree from the same institution; a Ph. D. from the University of Chicago in physiology and a medical degree from the University of Chicago. Certainly he was, under his testimony, qualified as a pharmacologist and there was no objection to his testimony. It is true that the transcript shows on page 56 that he was asked this question by the District Attorney:

Q. Do you have an opinion as to the effect this product would have if manufactured according to this formula and used according to the direc-

tions, the effect it would have on normal, healthy tissues in the vaginal tract?

Counsel for the defendants objected to that question upon the theory that 'There was no foundation laid for the witness as an expert; the fact that he graduated out of a lot of schools, he should show where he has experimented with it.' Well, that question just asks him whether he had an opinion, and, of course, the Court overruled the objection because that objection was not well taken. It would make no difference whether he was qualified in any field or not as an expert, the fact that he would be asked to testify whether or not he had an opinion. That is not incompetent evidence, and then after the Court overruled the objection he answered that question: 'I do have an opinion.' And he was then asked the question:

What is that opinion?

And there was no objection and he testified that:

I believe a substance as you have mentioned here, as a suppository, would tend to cause constriction of the tissues involved to which it was applied. I mentioned before, a precipitation of the protein here, and ultimately may result in ulceration in this area.

So, his opinions with reference to the drug, all of those opinions, were testified to by him without any objection on the part of the defendants whatsoever. His evidence was competent, and the Court cannot completely ignore it. It is in the record. There is no evidence on the part of the defendants in conflict therewith. What could the Court do other than to consider it? There is nothing else the Court can do. That is the way we have to try law suits.

"Specification 4. 'The Court erred in admitting into the record the testimony of Dr. Charles H. Proudfit.' As far as Dr. Proudfit is concerned, his qualifications were testified to by him and here is what he testified to:

I am a graduate of Indiana University; I graduated in 1934. I took my internship for the year rotation at Methodist Hospital in Indianapolis. I took four and a half years of gynecology and obstetrics in Mayos as a fellow and as a first.

Mr. LANE. What was that?

The WITNESS. Four and a half years of gynecology and obstetrics, which included a fellowship of three years and a first assistant of a year and a half.

Q. Are you licensed, doctor, in any state?

A. Yes, sir, I am licensed in Indiana.

Q. And are you a member of any professional Societies or associations?

A. I belong to the local St. Joseph County Medical Society; I belong to the State Medical Society; and I belong to the American Medical Association; and I belong to the American Academy of Gynecology and Obstetrics.

Q. Have you been certified by any of the boards, doctor?

A. Yes, sir, obstetrics and gynecology.

Q. What does that certification mean?

A. You have to have so many years of training in a special field before you are eligible for taking an examination for certification of the American Board, whichever it is called, case history reports that have to be sent in and an oral examination, and practical examination, including histology and pathology.

Q. In what year were you certified, doctor?

A. 1947.

"He testified that he was a gynecologist, a specialist in that field, and certainly under his testimony he was eminently qualified to express an opinion as to the effect of this drug, that is, these suppositories, used as they were intended by the defendants to be used. So there was no error, no objection to any of the questions calling for opinions by Dr. Proudfit, and that evidence went into the record without any objection.

"Specification 5. 'The Court erred in finding that the remedy in question was misbranded.' The labeling is false. There is no question about the fact that the drug is misbranded. There is no question about the admissibility of the label that accompanied the suppositories. It was placed thereon by the defendants, and here is a label that says that the suppository is a soothing

astringent for use at onset and duration of temporary minor vaginal irritations. Well, now, they are prescribed and labeled by the defendants to cure minor vaginal irritations, and yet in the label, right on down about midpart thereof the directions for the use of the suppositories, and then the label says 'so long as no irritations result, do not disturb for three days and nights.' So, the label shows on its face that the suppository may produce irritation of the vaginal tract, and yet users are informed thereby that it produces the very thing it is supposed to cure. I suppose if that happens, you are to get in touch with your doctor, I don't know.

"Specification 6. 'The Court erred in finding that said product had no therapeutic value.' On page 117 of the transcript this question was put by the Court: 'What, if any, therapeutic value is there in your opinion in a suppository or suppositories prepared from the ingredients compounded in paragraph five of the complaint, what therapeutic value?' And the expert said, 'Sir, I wouldn't know of any therapeutic value at all.' That is the reason the Court found that the drug had no therapeutic value. That is the evidence upon which the Court based its finding, and that evidence is clear and positive. What is the Court to find, that it did have therapeutic value when the undisputed evidence was that it had none? That is ridiculous.

"Specification 7. 'The Court erred in its finding No. 4 that said drug had no therapeutic value and was not efficacious and is harmful, and that the labeling thereof by the defendants is false and misleading, that said drug is misbranded.' Well, now, gentlemen, insofar as finding number 4 is concerned, this is what the Court found. 'Said drug has no therapeutic value and instead of being efficacious in the cure of minor vaginal irritations is harmful and the labeling thereof by the defendants is false and misleading and said drug is misbranded.' Now, that finding is based on the evidence contained in the transcript on pages 117 and 118. The Court has already read what the question was that was propounded to Dr. Proudfit as to the therapeutic value of the suppository. His answer was:

> Sir, I wouldn't know of any therapeutic value at all.

And then the doctor was asked the question:

> What in your opinion, doctor, would you say as to whether or not such suppository or suppositories, if used, would or would not be dangerous to the health of the patient when used?

And his answer

> In my opinion, any suppository containing the percentage that that suppository supposedly does, would be irritating even to normal mucous membrane, let alone to mucous membrane that has been inflamed or irritated by infection.

So, here is a suppository that the experts say is harmful. It does not cure minor irritations of the vaginal tract. It would produce them, and it would be injurious to the mucous membrane of the vaginal tract if used when already irritated. The next question is whether or not there would be any danger to the patient in using a suppository prepared from the formula, combined from those ingredients, whether there would be any danger to the health of the patient from the use of them as directed in paragraph three—that is paragraph three of the plaintiff's complaint. And his answer was 'Yes, my opinion is that they could be definitely a factor in impairing the health of the patient.' That is why the Court found as it did in its finding number 4. And it is based on the undisputed evidence which went in the record without any objection on the part of the defendants.

"Specification 8. 'The Court erred in its finding of fact number 5.' Well, number 5 is that, 'The use of said drug in accordance with the directions on the label will cause mucous membrane of the vaginal tract which is already irritated to become worse, and will cause healthy tissue to become irritated, and the irritations caused by its use would range from slight damage by the use of a single suppository to severe ulceration with continued use.' And, of course, that is what the doctor testified. He testified that it might produce an ulcerated condition in the mucous membrane of the vaginal tract. There is no question about the fact that that is the testimony, gentlemen, that is the evidence in the record, undisputed and it was admitted and went into the record without any objection on the part of the defendants whatsoever. Now, Dr. Oster on page

56 of the transcript was asked this question, 'What is that opinion?' And he answered:

> I believe a substance as you have mentioned here, as a suppository, would tend to cause constriction of the tissues involved to which it was applied. I mentioned before, precipitation of the protein here, and ultimately may result in ulceration in this area.

That is the testimony. It is undisputed. The Court cannot just ignore it. It is uncontradicted and that is the reason that the Court made its finding number 5.

"As far as finding number 6 of the Court is concerned, 'The use of said drug will not benefit any irritation of the vaginal tract but will produce irritation to the mucous membrane of the vaginal tract and when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, is dangerous to health.' That is what the testimony is, gentlemen, undisputed, uncontradicted in the record, and that is it.

"Specification 10. The Court in its finding No. 7 has misconstrued the facts as shown by the testimony and evidence in the record. Finding number 7 is that, 'The defendants have continued to distribute said Oak Balm Vaginal Suppositories in interstate commerce despite warnings that the drug was and is misbranded, and are now engaged in the introduction, sale, delivery for introduction and distribution in interstate commerce of said misbranded drug and will, unless enjoined, continue so to do.' Yes, gentlemen, that is the testimony. Page 48 of the transcript, the witness testified that he was in conversation with Mrs. Feather, one of the defendants, and he testified:

> I also told her that as she was aware, the Food and Drug Administration took the position that the high proportion of alum in the suppositories was considered by the Food and Drug to be dangerous to health, and she said that she was aware of that fact, and that sometime ago she had reduced the alum content of the suppositories but had received so many complaints that she restored the alum content to near its former level. In her conversation, she also told me of injuries, at least one person had received, through the use of the preparation and cited that as partial reason for the restoration of the alum to near its former level.

Well, she was aware of the fact that the Food and Drug Administration contended that the product was dangerous. Then, the defendants themselves offered the evidence that the product was being used at the time of the trial. They produced a witness by the name of Hallie Comer. That was a witness for the defendants, and this question was asked of her:

> Have you used the product known as Oak Balm Vaginal Suppositories?
> A. I have.
> Q. How long?
> A. This will be nine weeks.
> Q. You still use this product?
> A. Yes, sir.

That was at the time of the trial, well, that is the evidence. It is uncontradicted and undisputed and offered by the defendants themselves, and certainly there is no question about the validity of that finding of fact by the Court.

"Conclusion of law number 7 is based on the findings of the Court, and, of course, paragraph 2 of the decree of the Court is based on conclusion of law number 7.

"Gentleman, I do not know, maybe there is some way to try a law suit where you can be more fair and where the findings can be supported by the evidence to a greater extent, but I do not know how. Certainly, in my opinion, there is no merit to the motion for the new trial of the defendants, and the motion will be denied.

"Mr. Reporter, if you will be kind enough to prepare the opinion of the Court as announced from the bench, and for the benefit of counsel, it will be prepared in sufficient copies so that copies will be available to counsel, and it will be filed with the clerk as the opinion of the Court in ruling on the motion of the defendants for a new trial."

An appeal was taken to the United States Court of Appeals for the Seventh Circuit, which court, on 10–18–55, after consideration of argument and briefs of counsel, entered an order affirming the judgment of the lower court.

4742. **Nu Youth tablets.** (F. D. C. No. 36655. S. Nos. 40–225 L, 58–142 L.)

INFORMATION FILED: 7–28–55, S. Dist. Calif., against Frederic S. Weichman, t/a N-Y Distributing Co., Los Angeles, Calif.

SHIPPED: 1–15–54 and 1–20–54, from California to Arizona and Illinois.

LABEL IN PART: (Btl.) "Each tablet contains 5 mg. Methylandrostenediol suggested dosage. One tablet upon arising before breakfast and one tablet shortly before retiring. For adult males not for children or young adults Caution: Do not take more than dosage recommended. Continued use extending over six months to be avoided, except under supervision of a physician. Do not use in cases of cardiac and kidney disease, cancer of the prostate, defects of spermatogenesis, sterility or debilitation due to disease. Indications: Used in place of testosterone, methyltestosterone and testosterone propionate for its androgenic effect and as an anabolic agent * * * Nu Youth 60 Tablets."

ACCOMPANYING LABELING: Leaflets entitled "The Evidence" and undated letters addressed to "My Dear Friend" and signed by "Charles St. Regis" under the letterhead of N-Y Distributing Co.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the drug was a new, improved, safe sex hormone; that it could be used in place of testosterone, methyltestosterone, and testosterone propionate for its androgenic effect; and that it would be adequate and effective for providing renewed vigor, endurance, strength, and vitality in men over 40; for rejuvenating men by replenishing their deficient sex glands; for restoring masculine sex drive; for banishing mental fatigue; for boosting muscle power; for replenishing energy and endurance; for increasing mental alertness and ending irritability; for providing health, sexual aliveness, and emotional stability; for sex problems and impotency; for restoring waning physical and mental powers in men; for providing pep and vitality; and for providing the proper functioning and well-being of the human body; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling; 503 (b) (1)—the article was dispensed without a prescription therefor from a practitioner licensed by law to administer the drug; and 503 (b) (4)—the article was subject to 503 (b) (1), and at a time prior to dispensing, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 9–26–55. $200 fine.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4743. **Achromycin capsules.** (F. D. C. No. 37701. S. No. 12–707 M.)

QUANTITY: 52 100-capsule btls. at West Orange, N. J.

SHIPPED: During January 1955, from Bronx, N. Y., by Al Getzoff, t/a Re Ly On Drug Co.

LABEL IN PART: (Btl.) "Stellar Drug Company Wholesale Druggists 32 West 15th Street New York 11, N. Y. (100) Achromycin Capsules 250 mg. repacked (Lederle) #4768 Nov. 1956."

LIBELED: 3–8–55, Dist. N. J.

CHARGE: 502 (e) (2)—the label of the article when shipped failed to bear the common or usual name of the active ingredient, tetracycline; 502 (f) (1)—the labeling of the article failed to bear the information required by regulations

exempting the drug from bearing adequate directions for use in its labeling; 502 (l)—the article was composed wholly or partly of tetracycline, a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law; and 503 (b) (4)—the article was subject to the provisions of 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 4–14–55. Default—delivered to the Food and Drug Administration.

4744. Achromycin capsules and terramycin capsules. (F. D. C. No. 37927. S. Nos. 21–805/6 M.)

QUANTITY: 1 300-capsule btl. of *Achromycin capsules* and 2 250-capsule btls. of *terramycin capsules* at Philadelphia, Pa.

SHIPPED: 8–4–54, from Franklin Square, Long Island, N. Y., by Economy Buying Service, Inc.

RESULTS OF INVESTIGATION: Analyses showed that the *Achromycin capsules* contained 250 milligrams of tetracycline hydrochloride per capsule and that the *terramycin capsules* contained 250 milligrams of oxytetracycline hydrochloride per capsule.

LIBELED: 4–7–55, E. Dist. Pa.

CHARGE: 502 (b) (1)—the labels of the articles when shipped failed to bear the name and place of business of the manufacturer, packer, or distributor; 502 (f) (1)—the labels of the articles failed to bear adequate directions for use; 503 (b) (4)—the articles were subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 502 (l)—the *Achromycin capsules* purported to be and were represented as a drug composed wholly or partly of a derivative of chlortetracycline, and the capsules were not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: 7–27–55. Default—destruction.

4745. Nasal hydrocortisone, nasal solution, and Aureomycin capsules. (F. D. C. No. 37954. S. Nos. 13–661/3 M.)

QUANTITY: 7 ½-oz. vials of *nasal hydrocortisone*, 7 ½-oz. vials of *nasal solution*, and 1 100-capsule btl. of *Aureomycin capsules*, at Philadelphia, Pa.

SHIPPED: During January 1955, from Franklin Square, Long Island, N. Y., by Carl H. Kaplan, t/a Economy Buying Service, Inc.

LABEL IN PART: (Vial) "'Vasocort' Hydrocortisone Nasal" and "Drilitol Nasal Solution"; (btl.) "100 * * * Lederle Aureomycin Hydrochloride Crystalline Capsules 250 mg."

RESULTS OF INVESTIGATION: The *Aureomycin capsules* were shipped in a bulk container and were placed by the shipper in the above-described bottle when he delivered the capsules to the consignee, who supplied the bottle.

Partial analyses disclosed that the *nasal hydrocortisone* contained hydrocortisone and Paredrine; that the *nasal solution* contained thenylpyramine hydrochloride, Paredrine, and polymyxin B; and that the *Aureomycin capsules* contained about 135 milligrams of chlortetracycline per capsule.

LIBELED: 4–29–55, E. Dist. Pa.; amended libel filed 6–2–55.

CHARGE: 501 (b)—the *Aureomycin capsules* purported to be and were represented as a drug, the name of which is recognized in the United States Pharma-

copeia, and the strength of the article when shipped and while held for sale differed from the official standard;

502 (b) (1) and (2)—the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents;

502 (e) (2)—the labels of the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear the common or usual name of each active ingredient;

502 (f) (1)—the labeling of the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear adequate directions for use;

502 (f) (2)—the labeling of the *nasal solution* when shipped failed to bear such adequate warnings against unsafe methods and duration of administration, in such manner and form, as are necessary for the protection of users;

502 (l)—when shipped and while held for sale, the *Aureomycin capsules* purported to be and were represented as a drug composed wholly or partly of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law;

503 (b) (4)—the *nasal hydrocortisone* was a drug subject to 503 (b) (1), and its label when shipped failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–27–55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

4746. Glutamic acid tablets and wheat germ oil capsules. (F. D. C. No. 37655. S. Nos. 9–323 M, 9–325/6 M.)

QUANTITY: 24 100-tablet btls. of *glutamic acid tablets* and 44 400-capsule btls. and 36 100-capsule btls. of *wheat germ oil capsules* at West Los Angeles, Calif.

SHIPPED: Between 4–23–54 and 11–23–54, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Btl.) "100 Tablets Glutamic Acid 7.7 gr. Use: Anti-convulsant in petit mal. Caution: Federal law prohibits dispensing without a prescription. Dose: Eight tablets 3 times daily" and "Wheat Germ Oil Each capsule contains Wheat Germ Oil . . . 3 Minums (A refined cold pressed oil from Wheat Embryo.) The need for Wheat Germ Oil in human nutrition has been established. Dose: 1 or 2 capsules daily or prescribed by a physician. Caution: Federal law prohibits dispensing without a prescription."

LIBELED: 2–14–55, S. Dist. Calif.

CHARGE: *Glutamic acid tablets.* 502 (a)—the statement on the label of the article when shipped contained false and misleading representations that the article when taken as directed was effective as an anti-convulsant in petit mal; and 502 (f) (1)—the article failed to bear adequate directions for use, and it was not exempt from such requirement because of the label statement "Caution: Federal law prohibits dispensing without a prescription" since the article was not in the possession of a firm or person lawfully entitled to dispense prescription drugs.

Wheat germ oil capsules. 503 (b) (4)—the article was not a drug subject to 503 (b) (1), and its label when shipped bore the statement "Caution: Federal law prohibits dispensing without a prescription."

The *wheat germ oil capsules* were alleged also to be misbranded under the

*See also Nos. 4742–4745.

provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3–8–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4747. (F. D. C. No. 29458. S. Nos. 15–860 K, 41–953/4 K, 41–964/5 K, 60–679/80 K.)

INFORMATION FILED: 9–11–50, E. Dist. Wis., against Lyon Drug Co., a partnership, Milwaukee, Wis., and Walter G. Kopling, a partner.

CHARGE: Between 10–17–49 and 12–19–49, 3 sales of *Seconal Sodium capsules* and 4 sales of *Nembutal capsules* were made by the defendants without obtaining a physician's prescription, which acts resulted in the drugs being misbranded as follows: 502 (b) (2)—each drug failed to bear a label containing a statement of the quantity of contents; 502 (d)—each drug contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning: May be habit forming"; and 502 (f) (1)—the labeling of each drug failed to bear adequate directions for use.

DISPOSITION: On 10–9–50, the defendant filed a motion to suppress evidence. The matter came on for hearing before the court on 3–1–54; and, on 6–25–54, the court handed down the following opinion in denial of the motion:

TEHAN, *District Judge:* "The defendants, Lyon Drug Company, a partnership, and Walter G. Kopling, the manager and one of the partners, are charged in seven counts of an Information with violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. 331, et seq., particularly Section 331 (k). The defendants have now moved to suppress certain evidence and have it returned to them on the ground that it was seized in violation of their constitutional rights, and in violation of an immunity clause in Section 373 of the statute itself.

"The defendants allege in their motion that the evidence, consisting of information, data, drugs, labels and prescriptions, and obtained by two inspectors of the United States Food and Drug Administration, was obtained without a search warrant and without voluntary permission of any person authorized to give such permission, and that it was given only because the inspectors represented that they had the right under the law to receive and remove such information and material. Both the Government and the defendants filed affidavits relating the facts as to the manner in which the Govrenment obtained the evidence in question. Although the allegations of the affidavits filed by the opposing parties were not in substantial conflict, the Court ordered a hearing on the motion for the purpose of taking testimony.

"The testimony of Frank Thompson, Jr. and Charles C. Curry, who were employed as inspectors by the United States Food and Drug Administration, showed that they visited the defendants' drug store on December 20, 1949, during the usual business hours, for the purpose of conducting an inspection. They had visited the place several times previously getting refills on prescriptions. On this particular occasion when Curry was refused a refill on a prescription, he left the store momentarily, and then re-entered with Thompson. They introduced themselves as United States Food and Drug inspectors to the defendant, Kopling, showed him their credentials and stated that they wished to examine the files, pharmaceuticals, invoices and prescriptions. At their request, Kopling, without objection, or protest, allowed them to examine his drug inventory, invoice files, and prescription files, and provided them with drug samples and certain prescriptions which they requested from his files. In addition, he signed a statement which identified the drug samples as having come from the same bottles used in refilling the prescriptions and which also indicated the source from which he had received the drugs. Thomp-

*See also Nos. 4741–4746.

son and Curry further testified that Kopling willingly, cooperatively, and courteously provided them with everything which they requested.

"Kopling's testimony, together with the testimony of his pharmacist, Joel D. Leslie, was substantially the same as that of Thompson and Curry, and Kopling himself testified that he raised no objection to the search that the inspectors desired to make, and in fact stated that he was 'very cooperative' and that he had 'cooperated fully.' He further testified that there was never a 'demand' for the information on the part of the inspectors, and explained his position at the time of the inspection by stating that if a policeman came up to him and showed credentials, he, Kopling, would certainly answer any questions asked of him.

"The defendants' motion to suppress the evidence is based, first, upon their contention that any evidence obtained by the inspectors on December 20, 1949, was obtained under duress and should therefore be returned.

"The Court believes that the defendants' first contention to the effect that the evidence was taken under duress is not supported by the credible evidence in the case. The Court is convinced that the defendants made no objection to the inspection, and that the defendant, Kopling, acting both for himself and for the partnership, at the request of the inspectors, opened his files and records, and freely made available to them the samples, information, and papers, which the defendants now seek to suppress. Kopling not only consented willingly to the inspection, but, by his own testimony, was completely cooperative throughout, and aided and assisted the agents in their search. The record shows that he voluntarily signed statements relating to the receipt and sale of the drugs, that he searched his files and located and turned over to the inspectors certain prescriptions requested by them, and that he voluntarily sold them samples of drugs and accepted payment therefor.

"Defendants' position that duress existed rests primarily upon the fact that the inspectors introduced and identified themselves as Government agents before making their requests for information. That fact alone under the circumstances of this case is not sufficient to constitute duress. In the absence of any threats, intimidation or force, incriminating matter turned over to law enforcement officials by an accused may be used in evidence against him. *Zapp* v. *United States*, 328 U. S. 624 (1946); *United States* v. *MacLeod*, 207 F. 2d 853 (C. A. 7 1953).

"The second and final contention of the defendants is that the inspection and collection of samples was made pursuant to Title 21 U. S. C. A. Section 373, and that consequently they are entitled to the immunity provided by such section. Section 373 provides as follows:

> For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further*, That carriers shall not be subject to receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers. [Emphasis added.]

"The Court is of the opinion that this section is not applicable and consequently that the defendants' argument is without merit. First, it should be noted that Title 21 U. S. C. A. Sections 372 and 374 also authorize the type of an inspection, investigation and collection of samples conducted in the instant case, and secondly, since the information sought in the instant case was provided voluntarily by the defendants, it was not necessary to proceed under the statutory provisions of Section 373.

"The reason for the enactment of Section 373 is clearly indicated by its legislative history. The committee report which accompanied the Bill (H. R. Rep. #2139, 75th Cong., Third Session, 1938) states in part:

> While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. * * * The measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception * * *. Carriers are required to make available, for copying, records showing interstate shipments of suspected articles so that Federal jurisdiction can be established * * *. Section 703 (373) required interstate carriers and receivers to permit access to and the copying of all necessary records to show interstate shipment and thus establish Federal jurisdiction. This provision is necessary since some warehousemen and trucking concerns and even some railroads have refused to permit the copying of records which were essential to the institution of proceedings to control abuses of consumer health and welfare. The absence of such provision in the present law has been a definite handicap to its enforcement * * *. In short, the purpose of the provision here in question was to close an earlier loophole in the enforcement provisions of the act, which handicapped its enforcement, this handicap being caused by the refusal of certain carriers, if not others, to permit the copying of essential records. In other words, where, as was generally the case, these records were willingly made available to the Government, so that the Act could readily be enforced, the previous law was effective. But, in cases where this access and copying was refused, the section in question would apply to overcome such refusal, and eliminate such "handicap to its (the Act's) enforcement."

"The purpose in enacting Section 373, as is clearly indicated by the legislative history, was to enable the enforcement officials to obtain records of interstate shipment so that Federal jurisdiction could be established, and by its very terms, Section 373 is confined to records of interstate shipment.

"The defendants argue that they were placed in a position where if they refused to consent to the inspection they would be guilty of a misdemeanor (Title 21 U. S. C. A. 331 (e)), whereas by consenting to it they find themselves charged with a felony. However, as the section itself indicates, it is not a violation of law to refuse to allow inspection of interstate records upon a simple request of an inspector. It becomes unlawful only 'when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device or cosmetic to which such request relates.'

"The defendants' motion and arguments in support thereof are similar to those raised in the case of *United States* v. *Arnold Pharmacy*, 116 F. Supp. 310, 314. In that case the Court said:

> Considered, therefore, in the light of both the purpose of this statutory amendment and of its terms, it is clear that it is not intended to hamper the powers of the Government in protecting the public, but to add to its powers to that end. Thus since, under well settled principles, those who voluntarily turn over their records to the Government cannot object to their use in criminal proceedings, it can hardly be claimed that this statutory amendment was intended to prevent such use under such circumstances. On the other hand, it is clear both from the purpose of the amendment and its terms, that the section was intended to apply where access to the records was refused the Government. In that event, by proceeding under the statutory provision in question, the Government could obtain access to such records despite such refusal. But, if the Government did so proceed, then the "evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained."

"The Court is of the opinion that the evidence here in question was voluntarily turned over to the inspectors by its owners, that the conditions for the applicability of Section 373 did not exist, and that the Statute does not apply. The Court believes that *United States* v. *Crescent-Kelvan Co.*, 164 F 2d 582 (C. A. 3 1948) and *United States of America* v. *Scientific Aids Co., a partnership, et al.* (Cr. 268–53, U. S. Dist. Court, N. J., Jan. 19, 1954) support this view.

"Defendants' motion to suppress the evidence must therefore be denied."

On 10–12–54 a plea of guilty was entered by the partnership to counts 1, 2, 3, and 4 of the information and, by agreement of the parties, the charges against the partnership on counts 5, 6, and 7 and against the individual on all counts were dismissed. On 12–20–54, the court fined the partnership $700.

4748. (F. D. C. No. 34362. S. No. 878 L.)

INFORMATION FILED: 3–24–53, S. Dist. Fla., against Henry Gilman and Rudolph R. Scher, partners in the partnership of Park Pharmacy, Miami, Fla., and Meyer Colten, a pharmacist.

CHARGE: On 11–7–51, while held for sale, *Seconal Sodium capsules* were dispensed once without a prescription. Such act of dispensing resulted in the drug being misbranded as follows: 502 (b) (2)—the drug failed to bear a label containing an accurate statement of the quantity of contents; 502 (d)—the drug contained a chemical derivative of barbituric acid, and the label of the drug failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 502 (f) (1)—the labeling of the drug failed to bear adequate directions for use.

DISPOSITION: The defendants filed a motion to dismiss the information, and on 4–17–53, the motion was denied. Thereafter, the defendants entered pleas of nolo contendere, and on 1–6–56, Gilman and Scher were each fined $100 and Colten $50.

4749. (F. D. C. No. 33764. S. Nos. 1–940 L, 1–954 L, 1–961 L.)

INFORMATION FILED: 4–29–53, S. Dist. Fla., against Warfield Thirty-Sixth St. Corp., t/a Warfield Drug Co., Miami, Fla., James J. Weinberger, president of the corporation, and Louis Finkelstein and Ralph Swisko, pharmacists.

CHARGE: Between 12–3–51 and 1–28–52, while held for sale, *pentobarbital sodium capsules* were dispensed 3 times without a prescription. Such dispensing resulted in the drug being misbranded as follows: 502 (b) (2)—the drug failed to bear a label containing an accurate statement of the quantity of contents; 502 (d)—the drug contained a chemical derivative of barbituric acid, and the label of the drug failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 502 (f) (1)—the labeling of the drug failed to bear adequate directions for use.

DISPOSITION: The defendants filed a motion for dismissal of the information, and on 6–29–54, this motion was denied. The defendants then entered pleas of nolo contendere, and on 1–28–56, the court fined each defendant $100.

4750. **Herb mix.** (F. D. C. No. 37539. S. No. 16–094 M.)

QUANTITY: 4 340-lb. drums, 48 4-oz. bags, and 12 sample bags, each containing about 2 tablespoonsful, at Tacoma, Wash., in possession of Saunders' Health Service.

SHIPPED: 11–12–54, from New York, N. Y.

LABEL IN PART: (Bag) "Mixed Herbs No. One Contains: Yam, Culvers, Althea, Mandrake with Cascara."

ACCOMPANYING LABELING: A letter dated "July 23, 1954" and signed "Nina M. Moon" reading in part "Mixed Herbs #1 * * * saved me from an operation for gall-stones. Everyone who buys gets the same results as a liver cleanser." The letter was on display in front of the retail counter on the premises of Saunders' Health Service.

RESULTS OF INVESTIGATION: The article was shipped from New York, N. Y., in bulk drums and, after its receipt at Tacoma, Wash., by the consignee, a portion of the article was repacked into the bags described above.

LIBELED: 12–21–54, W. Dist. Wash.

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for gallstones and for cleansing the liver; and 502 (f) (2)—the article was essentially a laxative, and its labeling, while held for sale, failed to warn against use of the article when symptoms of appendicitis are present and failed also to warn that frequent or continued use of the article may result in dependence on laxatives.

DISPOSITION: 1–26–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4751. **Posterior pituitary injection.** (F. D. C. No. 37287. S. No. 88–418 L.)

QUANTITY: 44 cartoned vials at Buffalo, N. Y., in possession of Direct Laboratories, Inc.

SHIPPED: 2–24–53, from Chicago, Ill.

LABEL IN PART: (Carton & vial) "No. 2261 10 cc. vial Posterior Pituitary Injection (Surgical) Double U. S. P. strength Each 1 cc. represents: Posterior Pituitary 20 USP units Chlorobutanol 5 mg. (8/100 gr.) * * * Water for injection USP q. s. 1 cc. * * * Administration: Intramuscular or Subcutaneous. * * * Direct Laboratories, Inc. Buffalo 4, New York."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and after its receipt by the consignee, it was repackaged and relabeled. Examination showed that the article contained 73 percent of the declared posterior pituitary potency instead of 85 percent as required by the United States Pharmacopeia.

LIBELED: 10–4–54, W. Dist. N. Y.

CHARGE: 501 (b)—the strength of the article while held for sale differed from the standard for posterior pituitary injection set forth in the United States Pharmacopeia.

DISPOSITION: 11–4–54. Default—destruction.

4752. **Chorionic gonadotropin.** (F. D. C. No. 37649. S. No. 77–276 L.)

QUANTITY: 99 packages at Philadelphia, Pa.

SHIPPED: 8–16–54, from Los Angeles, Calif.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of chorionic gonadotropin potency.

LIBELED: 2–9–55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it was represented to possess; and 502 (a)—the label statement "Chorionic Gonadotropin (Lyophilized) 5,000 I. U." was false and misleading.

DISPOSITION: 4–4–55. Default—destruction.

4753. **Liver-folic acid B_{12}.** (F. D. C. No. 37509. S. No. 89–577 L.)

QUANTITY: 63 vials at Minneapolis, Minn.

SHIPPED: 9–3–54, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed the article contained approximately 70 percent of the declared amount of vitamin B_{12}.

LIBELED: 12–9–54, Dist. Minn.

*See also No. 4745.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it purported and was represented to possess, namely, 110 micrograms of vitamin B_{12} per cubic centimeter; and 502 (a)—the label statement "Each cc. contains: Liver Extract U. S. P. 10 mcgm. Cyanocobalamine. Vit. B_{12} 100 Mcg." was false and misleading.

DISPOSITION: 1–25–55. Default—destruction.

4754. Chocolated Cokozine. (F. D. C. No. 37631. S. No. 6–629 M.)

QUANTITY: 94 8-oz. btls. and 71 1-pint btls. at Cincinnati, Ohio.

SHIPPED: Between 1943 and 1950, from New York, N. Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of vitamin B_1.

LIBELED: 1–31–55, S. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it was represented to possess, namely, 10 milligrams of vitamin B_1 (thiamine hydrochloride) per fluid ounce; and 502 (a)—the label statement "Contains in One Fluid Ounce: * * * Thiamin hydrochloride. . . . 10 mg." was false and misleading.

The libel alleged also that two other articles, namely, thiamine chloride elixir and malt syrup with halibut liver oil, were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3–3–55. Default—destruction.

4755. Rauwolfia serpentina. (F. D. C. No. 37594. S. Nos. 11–927/8 M.)

QUANTITY: 1 barrel containing 86 lbs. and 2 100-lb. drums at Brooklyn, N. Y.

SHIPPED: (2-drum lot) 4–19–54, from Tuticorin, India, by J. M. L. Danusu & Co.; (1-barrel lot) 5–4–54, from Chicago, Ill., by Armour Laboratories.

LIBELED: 1–12–55, E. Dist. N. Y.

CHARGE: 501 (d) (2)—the article in each lot was represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part therefor when shipped; 502 (a)—the label designations (1-barrel lot) "Rauwolfia Serpentina" and (2-drum lot) "Pow. Rauwolfia Serpentina" were false and misleading since such designations represented and suggested that the article in each lot consisted wholly of *Rauwolfia serpentina*, which was not the case; and 502 (i) (3)—the article in each lot was offered for sale under the name of another drug.

DISPOSITION: 3–9–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4756. Testo-Glan Male Formula and Fem-Tone Female Formula. (Inj. No. 275.)

COMPLAINT FOR INJUNCTION FILED: 3–9–54, E. Dist. N. Y., against Leo Shine, t/a Glanex Products, Floral Park, N. Y.

LABEL IN PART: "Testo-Glan Male Formula Regular Strength Each capsule contains—Hormonal activity as found in wheat—Testosterone (Male Sex Hormone) . . . . 0.067 mcg. Vitamin E . . . . 0.034 mgms. Survival Factor . . . . + Vitamin B 1 5 mg. 500% MDR Vitamin B 2 3.5 mg. 175% MDR Niacinamide . . . . 15 mg. [or "Double Strength Each capsule contains—

*See also Nos. 4741, 4742, 4746, 4750, 4752–4755.

Hormonal activity as found in wheat—Testosterone (Male Sex Hormone) . . . . 0.067 mcg. Vitamin E . . . . 0.034 mgms. Survival Factor . . . . + Vitamin B 1 10 mg. 1000% MDR Vitamin B 2 7 mg. 350% MDR Niacinamide . . . . 30 mg."] Contents 60 Capsules Sole Distributors Glanex Products * * * Floral Park, N. Y. Directions As a dietary supplement, take 2 capsules daily" and "Fem-Tone Female Formula Contents 60 Capsules Each capsule contains—Hormonal activity as found in wheat—Estrone (Female Sex Hormone) 0.005 mcg. Vitamin E . . . . 0.034 mgms. Survival Factor . . . . + Vitamin B 1 5 mg. 500% MDR Vitamin B 2 3.5 mg. 175% MDR Niacinamide . . . . 15 mg. Sole Distributors Glanex Products 6 North Tyson Avenue Floral Park, N. Y. Directions As a dietary supplement, take 2 capsules daily."

ACCOMPANYING LABELING: Folder entitled "For Men Past 40 Testo-Glan The New Extra Safe Male Power Formula" and a form letter addressed to "Dear Friend" and beginning with the words "Men past 40 everywhere are praising Testo-Glan."

CHARGE: The complaint alleged that the defendant had been and still was introducing into interstate commerce the above-mentioned articles which were misbranded within the meaning of 502 (a) by reason of the following false and misleading representations in their labeling:

(1) That the *Testo-Glan Male Formula* (regular strength and double strength) contained physiologically active glandular substances; that the glandular constituents of the article were of value in overcoming glandular deficiencies in the human male; that the article would increase male power; that it was an adequate and effective treatment for male sexual weakness, mental depression, loss of appetite, digestive disturbance, loss of muscle power, listlessness, headaches, loss of vigor, nervousness, vague aches and pains, sleeplessness, and irritability; and that it contained hormonal activity equivalent to therapeutically significant amounts of testosterone;

(2) That the *Fem-Tone Female Formula* would restore sexual desire in women; that it was an adequate and effective treatment for fatigue, loss of appetite, nervousness, dizziness, headaches, vague aches and pains, weakness, mental depression, and sleeplessness; and that it contained hormonal activity equivalent to therapeutically significant amounts of estrone.

The complaint alleged further that there were no known methods of demonstrating the presence or absence of the minute quantities of testosterone activity claimed to be present in the *Testo-Glan Male Formula* and the minute quantities of estrone activity claimed to be present in the *Fem-Tone Female Formula;* that the commonly employed therapeutic dose of testosterone given orally was at least 1,000 times the quantity that would be supplied in the recommended dosage of the *Testo-Glan Male Formula* based on the label statement of testosterone activity content; that the quantity of estrone activity claimed to be present in the *Fem-Tone Female Formula* was likewise totally insignificant; that the statements in the labeling of the articles conveyed to the usual and ordinary purchaser the impression that the *Testo-Glan Male Formula* contained hormonal activity equivalent to therapeutically significant amounts of testosterone and that the *Fem-Tone Female Formula* contained hormonal activity equivalent to therapeutically significant amounts of estrone, whereas such was not the case; and, that even if the articles did contain significant amounts of hormones, the articles would not accomplish the rejuvenating effects claimed for them.

DISPOSITION: 4-19-54. The defendant having consented, the court entered a decree permanently enjoining the defendant against the introduction into inter-

state commerce of "Testo-Glan Male Formula" (regular strength and double strength) and "Fem-Tone Female Formula," or any similar article of drug which would bear a label or would be accompanied by labeling containing false and misleading representations of the nature alleged in the complaint.

4757. Testo-Glan Male Formula. (Inj. No. 275.)

PETITION FILED: On 9–15–54, in the E. Dist. N. Y., the U. S. attorney filed a petition for an order to show cause why Leo Shine, t/a Glanex Products and Medical Products, Floral Park, N. Y., should not be punished for criminal contempt of the permanent injunction which had been entered against him on 4–19–54 (preceding notice of judgment No. 4756).

CHARGE: The petition alleged that, following the entry of the injunction, and between 4–28–54 and 5–27–54, the defendant caused interstate shipments of *Testo-Glan Male Formula* (regular strength and double strength) to be made from Floral Park, N. Y., to Dayton and Niles, Ohio; Norfolk, Va.; Los Angeles, Calif.; Chicago, Ill.; Atlanta, Ga.; and Hartford, Conn.; that, when so shipped, the article was misbranded under 502 (a) in that its labeling contained false and misleading representations that the article contained physiologically active glandular substances; that the glandular constituents of the article were of value in overcoming glandular deficiencies in the human male; that the article would increase male power; that it was an adequate and effective treatment for male sexual weakness, mental depression, loss of appetite, digestive disturbance, loss of muscle power, listlessness, headaches, loss of vigor, nervousness, vague aches and pains, sleeplessness, and irritability; that it contained hormonal activity equivalent to therapeutically significant amounts of testosterone; and, that by reason of such shipments, the defendant was in criminal contempt of the permanent injunction.

DISPOSITION: On 9–16–54, the order to show cause was issued, and on 10–11–54, the defendant pleaded guilty to violation of the injunction. On 11–14–54, the court fined the defendant $500.

4758. Alfa-Tone and Cab-Ext (2 seizure actions). (F. D. C. No. 37357. S. Nos. 64–766/7 L.)

QUANTITY: 1,524 unlabeled 90–tablet btls. and 250 labeled 90–tablet btls. of *Alfa-Tone* and 650 unlabeled 50–tablet btls. and 500 labeled 50-tablet btls. of *Cab-Ext* at Milton-Freewater, Oreg., in the possession of Dr. A. V. Downs, D. C.

SHIPPED: 7–7–54 and 7–14–54, from Lamar, Colo.

LABEL IN PART: (Btl.) "Alfa-Tone Each tablet contains 4 grs. water soluble Alfalfa Extract. 2 grs. of Alfalfa Seed Extract. 0.1 gr. of Chlorophyll" and "Cab-Ext Each tablet contains 400 Mg. of cabbage extract. As an aid in relieving ulcers and inflammation of stomach."

ACCOMPANYING LABELING: Loose labels designated "Alfa-Tone" and "Cab-Ext" and leaflets designated "Alfa-Tone As An Aid For Hay Fever, Low Vitality, Arthritis, Neuritis, Anemia, and Low Blood Pressure" and "Cabbage Juice."

RESULTS OF INVESTIGATION: Both articles were shipped from Lamar, Colo., in unlabeled bottles, and, upon their receipt by the consignee, the above-described labels were applied to a number of bottles. The leaflets were printed locally for the consignee and were distributed with the articles to various health store accounts serving the retail trade.

LIBELED: On or about 1–25–55, Dist. Oreg.

CHARGE: 502 (a)—the labeling of the articles while held for sale contained false and misleading representations that the *Alfa-Tone* was an adequate and

effective treatment for hay fever, low vitality, arthritis, neuritis, anemia, low blood pressure, and diabetes, and that the *Cab-Ext* was an adequate and effective treatment for ulcers and inflammation of the stomach.

DISPOSITION: 2–18–55. No claimant having appeared, the court entered decrees of condemnation and ordered that the articles be destroyed. Thereafter, a motion was made by Dr. A. V. Downs to set aside such decrees, and on 9–20–55, the court handed down the following decision on the motion:

SOLOMON, *District Judge:* "The motion to set aside the decree in condemnation in each of the above cases is denied.

COMMENT

"The respondent seeks to set aside and vacate the Decree of Condemnation entered in both of the cases on the 18th day of February, 1955. In Civil 7819, the court ordered 984 bottles of tablets labeled 'Alfa-Tone,' together with 500 product labels and 100 descriptive leaflets destroyed. In Civil 7820, the court ordered 480 bottles of tablets labeled in part 'Cab-Ext,' together with 200 descriptive leaflets destroyed.

"There is no contention that the procedural requirements governing these cases have not been strictly met. The respondent was given ample time within which to answer the libel or otherwise appear, and he failed to do so.

"However, respondent contends that the tablets themselves are not harmful or deleterious and that if the leaflets which accompanied the tablets are destroyed, the legitimate purposes of the Federal Food, Drug, and Cosmetic Act will have been accomplished.

"I have examined the report of the analyses of the tablets made by the Charlton Laboratories for the respondent and by the Division of Nutrition of the Department of Health, Welfare, and Education for the libelant. Neither report shows that the tablets are themselves either harmful or deleterious. However, I am convinced that these tablets will serve no worthwhile purpose in the treatment of disease or in the remedying of nutritional deficiencies.

"The accompanying literature indicates that wild and unsupported claims were made concerning the effectiveness of these tablets in the treatment of disease. Even though the literature is destroyed, the return of these tablets to the defendant would, in all probability, result in similar claims being made orally. In my opinion, these tablets are salable only if accompanied by false and misleading statements, and their return to the defendant will only lead to exploitation of the people to whom they are sold."

4759. Hyrocain. (F. D. C. No. 37097. S. No. 64–762 L.)

QUANTITY: 49 display cartons, 12 cartoned tubes each, at Seattle, Wash.

SHIPPED: 6–8–54, from New York, N. Y., by the American Pharmaceutical Co.

LABEL IN PART: (Tube) "APC One Ounce Hyrocain Antibiotic, Antihistaminic And Anesthetic Cream Containing per Gram: Pyrilamine Maleate 10 mg., Benzocaine 10 mg., Tyrothricin 0.5 mg., in a special soothing, non-irritant, non-staining washable base."

ACCOMPANYING LABELING: Leaflet designated "Completely New! Antibiotic, Anesthetic, Antihistaminic Cream Helps Heal," a 2-page letter designated "Hyrocain A New Antibiotic and Anaesthetic Cream," and window banners designated "Hyrocain Stops Itch."

LIBELED: 9–21–54, W. Dist. Wash.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, eczema, skin infections, folliculitis, seborheic dermatitis, nummular eczema, neurodermatitis, and herpes genitalis; and the above-mentioned 2-page letter contained the statement "In order for this product to be released to the public it had to go through clinical testing in a leading allergy clinic and evidence presented to the Food and Drug Administration to

prove the efficacy, etc., of HYROCAIN," which statement represented and suggested that the Food and Drug Administration considers the article effective in the conditions and for the purposes for which it was offered, and which was false and misleading since the Food and Drug Administration does not consider the article effective in all of the conditions and for all of the purposes for which the article was offered.

DISPOSITION: 11–24–54. Consent—claimed by American Pharmaceutical Co. and relabeled.

4760. **Cacodyne.** (F. D. C. No. 33297. S. No. 33–012 L.)

QUANTITY: 20,300 ampuls, 10 cc. each, of *Cacodyne* (Colloidal Isotonic Iodine Solution) and 20,300 ampuls, 1 cc. each, of *Cacodyne* (Sodium Cacodylate) at Chicago, Ill., in possession of Research Medications, Inc.

SHIPPED: Between 9–1–50 and 12–19–51, from Tuckahoe and New York, N. Y.

LABEL IN PART: "10 cc. Size Cacodyne Each 10 cc. contains 0.2 percent Colloidal Isotonic Iodine Solution" or "Cacodyne Each cc. contains 7 gr. of Sodium Cacodylate (Arsenic derivative)."

ACCOMPANYING LABELING: Brochures entitled "Cacodyne An Isotonic Colloidal * * * for all arterial diseases" and reprints entitled "A Regimen for Restoration of Cardiovascular Reserve," "A New Management for the Sustained Relief of Angina Pectoris and Coronary Disease," "Decisiveness Imperative in Cardiovascular Management," and "Cardiovascular Disease, Its Treatment Based on Control of Hypertension and Restoration of Coronary Efficiency."

RESULTS OF INVESTIGATION: The articles, after their receipt at Chicago, Ill., were in part repackaged by the consignee, Research Medications, Inc., into combination packages containing 1 ampul of each article; and, when shipments of the repackaged articles were made by the consignee, there would be enclosed in the shipping container a copy of the above-mentioned brochure containing the statement "Reprints and other information on request."

LIBELED: 6–20–52, N. Dist. Ill.

CHARGE: 502 (a)—the labeling accompanying the articles while held for sale contained false and misleading representations that the articles were an adequate and effective treatment for all arterial diseases and all forms of circulatory impairment.

DISPOSITION: Research Medications, Inc., claimant, consented to the entry of a decree, and on 6–26–52, an order was entered condemning the articles and providing for their release to the claimant for the purpose of bringing them into compliance with the law. Thereafter, a dispute arose between the claimant and the Government as to the disposition of certain of the literature accompanying the articles, and the claimant filed a petition requesting the court to vacate the consent decree and to set the matter down for a hearing on its merits.

On 12–18–52, the court entered an order which permitted the claimant to file an answer, but left the consent decree standing as security; the court further ordered that that portion of the article which bore labeling which had been approved by the Food and Drug Administration during its negotiations with the claimant be released to the claimant, but that the accompanying labeling be held intact. Thereafter, the claimant filed a motion for particulars, or for more definite allegations, which motion was granted by the court on 12–24–52. The information requested by such motion was furnished by the Government

on 1–26–53. The claimant, on 2–4–53, filed an answer denying that the articles were misbranded as alleged.

Subsequently, the Government served interrogatories upon the claimant. The claimant objected to certain of the interrogatories; however, the court, on 5–11–53, overruled the objections and ordered the claimant to answer all interrogatories. Interrogatories then were served upon the Government by the claimant and were answered. Thereafter, the Government filed a request for admissions. The claimant subsequently withdrew its answer, and the court, on 3–2–54, with the consent of the claimant and the Government vacated the order entered on 12–18–52, an act which left the consent decree operative. The drug was satisfactorily relabeled, and the accompanying literature was destroyed.

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PRODUCTS

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[4] (4747) Prosecution contested. Contains opinion of the court.
[5] (4741) Injunction issued. Contains opinions of the court, findings of fact, and conclusions of law.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4758) Seizure contested. Contains opinion of the court.
[2] (4756) Injunction issued.
[3] (4757) Contempt of injunction.
[4] (4747) Prosecution contested. Contains opinion of the court.
[5] (4741) Injunction issued. Contains opinions of the court, findings of fact, and conclusions of law.

U. S. GOVERNMENT PRINTING OFFICE: 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4761–4780

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation or which were dismissed after trial; (2) criminal proceedings which were terminated upon pleas of guilty; (3) injunction proceedings terminated with the entry of injunctions; and (4) contempt proceedings for violation of an injunction which were dismissed. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal, injunction, and contempt proceedings are against the *firms or individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *September 14, 1956.*

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*For presence of a habit-forming narcotic without warning statement, see No. 4761; omission of, or unsatisfactory, ingredients statements, No. 4761; sale under name of another drug, No. 4774; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4761; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4761.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4761–4780

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2), an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (i) (3), the article was offered for sale under the name of another drug; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of a kind of chlortetracycline or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4761. Steclin capsules, Altepose tablets, and Feosol tablets. (F. D. C. No. 37952. S. Nos. 21–814/5 M, 21–817 M.)

QUANTITY: 1 btl. containing 430 *Steclin capsules*, 1 btl. containing 300 *Altepose tablets*, and 1 btl. containing 1,900 *Feosol tablets* at Philadelphia, Pa.

SHIPPED: 11–12–54 and 2–5–55, from Long Island, N. Y., by Carl H. Kaplan, t/a Economy Buying Service, Inc.

LABEL IN PART: (Btl.) "500 Steclin," "1000 Altepose," and "Feosol Tab."

LIBELED: 4–28–55, E. Dist. Pa.

CHARGE: 502 (b) (1)—the three articles when shipped failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; 502 (b) (2)—the *Steclin capsules* and *Feosol tablets* failed to bear labels containing an accurate statement of the quantity of contents; 502 (d)—the *Altepose tablets* contained a quantity of vinbarbital, a habit forming derivative of barbituric acid, and its label failed to state the quantity or proportion of such derivative and in juxtaposition therewith the statement: "Warning: May Be Habit Forming"; 502 (e) (1)—the label of the *Steclin capsules* failed to bear the common or usual name of the drug; 502 (e) (2)—the label of the *Altepose tablets* and *Feosol tablets* failed to bear the common or usual name of each active ingredient; 502 (f) (1)—the labeling of the three

articles failed to bear adequate directions for use; 502 (l)—the *Steclin capsules* purported to be and were represented as a drug composed wholly or partly of a derivative of chlortetracycline, and they were not from a batch with respect to which a certificate or release had been issued pursuant to law; and 503 (b) (4)—the *Steclin capsules* and the *Altepose tablets* were drugs which were subject to the provisions of 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–27–55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

4762. Gray, white, and pink tablets containing, among other ingredients, amphetamine phosphate racemic, thyroid, atropine sulfate, and phenobarbital. (F. D. C. No. 35590. S. Nos. 64–264/6 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against Prentiss George Jones, a pharmacist, Anchorage, Alaska.

CHARGE: On 9–2–53, a quantity of *gray, white, and pink tablets containing, among other ingredients, amphetamine phosphate racemic, thyroid, atropine sulfate, and phenobarbital*, was caused, after shipment in interstate commerce, to be held for sale in a small bottle which failed to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," contrary to the provisions of 503 (b) (4).

PLEA: Guilty.

DISPOSITION: 6–24–55. $50 fine.

4763. Ascoramide tablets and Denta-Serts. (F. D. C. No. 38181. S. Nos. 18–891 M, 18–899 M.)

QUANTITY: 33 btls. containing 100 *Ascoramide tablets* each and 1 btl. containing 100 *Denta-Serts* at Chattanooga, Tenn.

SHIPPED: On an unknown date, from Columbus, Ohio, by Warren-Teed Products Co.

LABEL IN PART: (Btl.) "100 C. T. Creased * * * Warren-Teed Tablets Ascoramide Each tablet contains: Nicotinamide 50 mg., Ascorbic Acid 50 mg., Lactose Q. S." and "100 C. T. * * * Warren-Teed Denta-Serts (Sulfanilamide with Chlorophyll Wedges) Each compressed wedge contains sulfanilamide 0.12 Gm. (2 grs.) with chlorophyll For local chemotherapeutic action as an aid in preventing infection and dry socket and to aid in healing."

LIBELED: 6–15–55, E. Dist. Tenn.

CHARGE: *Ascoramide tablets.* 502 (a)—the statement on the label of the article when shipped "for the treatment of deficiency conditions associated with Vincent's infection, gingivitis and bleeding gums" was false and misleading since the article was not an effective treatment for such conditions.

Denta-Serts. 503 (b) (4)—the article was a drug subject to 503 (b) (1), and, when shipped, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–25–55. Default—destruction.

*See also No. 4761.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4764. B-amino-complex (B-amino-BAC-complex or Unitone) tablets. (Inj. No. 267.)

COMPLAINT FOR INJUNCTION FILED: 9–28–53, S. Dist. N. Y., against Barrows Chemical Co., Inc., and Unitone Corp., both of New York, N. Y., and against Joseph Barrows, president of the corporations, to enjoin the interstate shipment of an article in tablet form known by the trade names of "B-Amino-Complex," "B-Amino-BAC-Complex," and "Unitone." Amended complaint filed on or about 10–30–53.

LABEL IN PART: "B-Amino-Complex [or "B-Amino-BAC-Complex" or "Unitone"] * * * VITAMINS Daily dose of 6 tablets contains: Vitamin B_1 (Thiamine Hydrochloride) 18.0 mg. Vitamin B_2 (Riboflavin) 27.0 mg. Niacinamide 180.0 mg. Vitamin B_6 (Pyridoxine Hydrochloride) 3.0 mg. High Potency Yeast 200.0 mg. Brewer's Type Yeast 200.0 mg. Inositol 60.0 mg. Choline Hydrochloride 60.0 mg. Panthenol (Equal to Cal. Pantothenate 30 mg.) 26.1 mg. AMINO ACIDS (Vitagenic Accelerators) as contained in Yeast Protein Enzymatic Hydrolysate 1.0 Gm. Fortified with Nucleic Acid 100.0 mg. Glutamic Acid 50.0 mg. Glycine 50.0 mg. Cysteine Hydrochloride 25.0 mg. DI AND TRI-VALENT MINERALS Iron (Ferric Citro Pyrophosphate Soluble) 28.8 mg. Copper (Copper Sulfate) 2.1 mg. Magnesium (Magnesium Sulfate) 5.9 mg. Zinc (Zinc Sulfate) 1.4 mg. Cobalt (Cobalt Sulfate) 1.3 mg."

CHARGE: The complaint alleged that the defendants were engaged in the business of manufacturing, distributing, and selling the above-mentioned article and that, for the purpose of explaining the uses of the article and promoting its distribution, the defendants caused the article to be accompanied by labeling consisting of leaflets entitled "Amazing Medical Discovery," "If Your Body Could Talk It Would Say," and "A Revolutionary Advance in Nutrition," placards entitled "Amazing Discovery Checks Deafness, Helps Restore Hearing, Clinically Tested—Come in For Free Booklet," "BAC," and "For the One in Five Who is Hard of Hearing," and publications entitled "Nutritional Guide Better Nutrition Better Health" and "Health and Nutrition News Spring Summer 1953."

The complaint alleged further that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of the article which was misbranded as follows:

502 (a)—the label of the article and the above-mentioned accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for deafness; that it was a new and amazing discovery and a revolutionary advance as a food supplement which, when used as directed, would supply an important quantity of protein; that it was needed to activate the eyes, ears, lungs, liver, intestines, muscles, brain, heart, stomach, kidneys, and the entire body; that it would supply vitamins, proteins, and minerals in the correct proportions, and balanced amounts to stimulate the body to work as nature intended; that it would endow the user with vibrant life, health, and energy; that it would enable the liver to convert more than normal amounts of carbohydrates into energy; that it would supply increased energy to the heart, lungs, muscles, liver, and other important organs; that it would supply missing enzymes necessary to carry on body functions, such as growth, repro-

*See also No. 4761.

duction, secretion, nerve conduction, muscular contraction, etc.; that it would transfer fatigue to quick energy, prevent and correct dysfunction in the energy conversion chemistry of body functioning; and that it would reactivate all enzyme systems necessary for healthy body functioning and would activate the body cells to function as nature intended;

502 (a)—the following statements in the accompanying leaflet entitled "If Your Body Could Talk It Would Say," namely, "'Unbalanced B. Vitamins May Be Dangerous' . . . says The Journal of the American Medical Association in an Editorial of September 1, 1945. They say further . . . 'Extensive scientific evidence has revealed that if B Vitamins are administered in other than balanced proportions they may create Vitamin Deficiencies rather than cure them' . . . still quoting the JAMA, the Editorial continues 'Many B–Complex preparations available to the physician and public today are definitely unbalanced . . . either too much thiamine or not enough riboflavin, niacin, or pyridoxine,'" were false and misleading since the quotations contained in such statements did not appear in an editorial in the September 1, 1954, issue of The Journal of the American Medical Association; and,

502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of deafness, which was the condition for which the article was intended to be used and for which it was offered in the accompanying labeling described above and in advertising matter.

The complaint contained also allegations concerning the misbranding of the article under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 22449.

Disposition: 11–18–54. The defendants having consented to the entry of a decree, the court entered a decree of permanent injunction. The decree enjoined the defendants against introducing into interstate commerce the above-mentioned article or any similar article accompanied (1) by the above-mentioned leaflets and placards or (2) by any written, printed, and graphic matter representing that the article was a new and amazing discovery and a revolutionary advance as a food supplement which, when used as directed, would supply an important quantity of protein; that the article was needed to activate the eyes, ears, lungs, liver, intestines, muscles, brain, heart, stomach, kidneys, and the entire body; that it would supply vitamins, proteins, and minerals in the correct proportions, and balanced amounts to stimulate the body to work as nature intended; that it would endow the user with vibrant life, health, and energy; that it would enable the liver to convert more than normal amounts of carbohydrates into energy; that it would supply increased energy to the heart, lungs, muscles, liver, and other important organs; that it would supply missing enzymes necessary to carry on body functions, such as growth, reproduction, secretion, nerve conduction, muscular contraction, etc.; that it would transfer fatigue to quick energy, prevent and correct dysfunction in the energy conversion chemistry of body functioning; and that it would reactivate all enzyme systems necessary for healthy body functioning and would activate the body cells to function as nature intended; or (3) by written, printed, and graphic matter representing that the article would check, cure, or be an adequate and effective treatment for deafness or hard of hearing. The decree provided, however, that the defendants could introduce the article into interstate commerce if it was accompanied by written, printed, or graphic matter clearly limiting and describing the use of the article only as follows:

For cases in which the cause of deafness has been medically diagnosed as hearing nerve deafness due to carbohydrate metabolic disturbance as indicated by high pyruvic acid level in the blood (higher than 2 mg. per 100 cc. under basal conditions), this product may be of value when used in conjunction with other suitable treatment prescribed by your physician. A blood test is necessary to determine whether the level of pyruvic acid in the blood is high.

The decree further enjoined the defendants against introducing the article into interstate commerce unless it was accompanied by written, printed, or graphic matter which clearly stated and enumerated every disease, condition, symptom, and purpose for which the article was intended to be used and for which it was represented by any means to the public.

4765. Ovarian extract, corpus luteum extract, Pit-Ovarin, and anterior pituitary extract. (F. D. C. No. 37586. S. Nos. 14–603/6 M.)

QUANTITY: 66 vials of *ovarian extract*, 77 vials of *corpus luteum extract*, 91 vials of *Pit-Ovarin*, and 22 vials of *anterior pituitary extract* at St. Louis, Mo.

SHIPPED: Between 10–7–54 and 12–1–54, from Philadelphia, Pa., by National Drug Co.

LABEL IN PART: (Vial) "List #167 Multiple Dose Vial 15 cc. Ovarian Extract * * * Each cc. contains the water and alcohol soluble extractives derived from 40 grains of fresh Ovarian Glands with Chlorobutanol 0.5% * * * For intramuscular use in non-specific therapy," "List #80 Multiple Dose Vial 25 cc. Extract Corpus Luteum * * * Each cc. contains the water soluble extractives derived from 18 grains of Chlorobutanol * * * 0.5% Contains no known hormonal therapeutic activity. For Intramuscular Use In Ovarian Dysfunction," "List #283 Multiple Dosé Vial 25 cc. Pit-Ovarin * * * Each cc. contains water soluble solids from 20 gr., fresh Whole Ovary and from 5 gr., fresh Anterior Pituitary gland with Procaine Hydrochloride 1% and Chlorobutanol * * * 0.5% For use in nonspecific therapy," and "List #118 Multiple Dose Vial 25 cc. Anterior Pituitary Extract * * * Each cc. contains the water soluble ingredients obtained from 18½ grains of fresh anterior pituitary lobe tissue with Chlorobutanol 0.5%."

LIBELED: 1–7–55, E. Dist. Mo.

CHARGE: 502 (a)—the statement on the label of the *corpus luteum extract* when shipped, namely, "For * * * Use In Ovarian Dysfunction," was false and misleading as applied to the article, which would be of no value in the treatment of ovarian dysfunction, and the label statements of such article "Contains no known hormonal therapeutic activity" and "For * * * Use In Ovarian Dysfunction" were misleading when considered together since they were mutually contradictory; and 502 (f) (1)—the labeling of all of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from that requirement.

DISPOSITION: 2–3–55. Default—destruction.

4766. Elemin vitamin and mineral tablets. (F. D. C. No. 37520. S. Nos. 5–566/7 M.)

QUANTITY: 6 cases, 24 retail cartons each, and 10 cases, 12 retail cartons each, at Milwaukee, Wis.

SHIPPED: Between 11–24–53 and 4–6–54, from Berkeley, Calif.

LABEL IN PART: (Carton) "Contents 360 Tablets * * * Elemin * * * G & J Multiple Vitamins Supreme Formula * * * 240 Mineral Tablets"; "Elemin G & J Royal Formula 360 Mineral Tablets"; and "Elemin G & J Formula * * * 720 Minerals * * * 300 Vitamins * * * This package contains a 6 months' supply."

LIBELED: 12–13–54, E. Dist. Wis.

CHARGE: 502 (f) (1)—The labeling of the tablets while held for sale failed to bear adequate directions for use in the treatment and prevention of colds, sinus infections, heart trouble, diabetes, asthma, high blood pressure, ulcerated stomach, and arthritis, which were the conditions for which the tablets were offered orally by John P. Sheeran, a representative of G & J Distributors, Berkeley, Calif., on 11–16–54, while promoting the sale of "Elemin" to persons understood by him to be prospective purchasers of the tablets.

DISPOSITION: 1–14–55. Default—destruction.

4767. Elemin vitamin and mineral tablets. (F. D. C. No. 37048. S. Nos. 64–759/60 L.)

QUANTITY: 411 pkgs. at Boise, Idaho, in possession of George R. Wingert.

SHIPPED: Between 6–2–54 and 7–7–54, from Berkeley, Calif.

LABEL IN PART: (Pkg.) "Contents 360 Tablets * * * Elemin * * * G & J Multiple Vitamins Supreme Formula * * * 240 Mineral Tablets" and "Elemin G & J Royal Formula * * * Mineral Tablets * * * G & J Multiple Vitamins."

LIBELED: 8–26–54, Dist. Idaho.

CHARGE: 502 (f) (1)—the labeling of the articles while held for sale failed to bear adequate directions for use in the treatment of arthritis, bursitis, diabetes, hay fever, heart trouble, kidney infection, nervous disorders, throat irritation, and sinus trouble, which were the conditions for which the tablets were offered orally by George R. Wingert, regional manager for the distribution of "Elemin," on 6–28–54, in Boise, Idaho.

DISPOSITION: 12–23–54. G & J Distributors, Inc., Berkeley, Calif., and George R. Wingert, owner and claimant of the articles, having consented to the entry of a decree, judgment was entered ordering that the tablets be released to G & J Distributors for the purpose of changing the name of the tablets. The tablets subsequently were released and destroyed.

4768. Alfalfa tablets and alfalfa seed. (F. D. C. No. 37047. S. Nos. 85–891/2 L.)

QUANTITY: 2 20,000-tablet tins, 12 500-tablet btls., and 22 300-tablet btls. of *alfalfa tablets*, and 1 25-lb. bag and 19 1-lb. pkgs. of *alfalfa seed* at Minneapolis, Minn , in possession of Cayol Food Center Co.

SHIPPED: 4–5–54, and 6–8–54, from Huntington Park and Fresno, Calif.

LABEL IN PART: (Btl.) "Alfalfa Tablets 8 Grain Contains Dehydrated Alfalfa with vegetable binder Distributed By Cayol Food Center Co. 812 La Salle Avenue Minneapolis, Minn. * * * Three tablets three times daily"; (pkg.) "Alfalfa Seed Cayol Food Center Company Use Three Tbsp Seed To One Qt. Water. Steep Five To Thirty Minutes Drink Two To Four Cups Daily."

ACCOMPANYING LABELING: Booklet entitled "Medicinal Value of Natural Foods."

RESULTS OF INVESTIGATION: The tablets in the bottles and the seed in the packages had been shipped in bulk and thereafter repackaged and relabeled by the consignee. A copy of the above-mentioned booklet, opened to the pages on which the subject headed "Alfalfa" was bracketed in red pencil, was on display in the consignee's store window, along with a number of bottles of the *alfalfa tablets* and packages of the *alfalfa seed.*

LIBELED: 8–17–54, Dist. Minn.

CHARGE: 502 (a)—the accompanying labeling of the articles while held for sale contained false and misleading representations that the articles were effective in the treatment of diabetes, tuberculosis, rheumatism, Bright's disease, toxemia, jaundice, neuralgia, insomnia, nervousness, syphilis, constipation, lumbago, hardening of the arteries, dropsy, prostatitis, anemia, skin eruptions, poor complexion, inflammation of the bladder, colds, fevers, and gonorrhea; and that they were effective to build blood, to build teeth and bones, to stimulate kidneys, to aid peristalsis of the bowels, to increase appetite, to strengthen digestive glands, to increase assimilation of foods, and to increase body weight; and 502 (f) (1)—the labelings of the articles failed to bear adequate directions for use.

DISPOSITION: 1–10–55. Consent—claimed by Cayol Food Center Co. and relabeled.

4769. Vaginal suppositories and vaginal tablets. (F. D. C. No. 37697. S. Nos. 10–303/4 M.)

QUANTITY: 23 boxes of *vaginal suppositories* and 232 boxes of *vaginal tablets* at St. Paul, Minn.

SHIPPED: (232-box lot) 2–26–54, from Chicago, Ill., by Savoy Drug & Chemical Co.; (23-box lot) 12–22–54, from Cedar Rapids, Iowa, by Paul Maney Laboratories.

LABEL IN PART: (Box) "Warner Renowned Vaginal Suppositories * * * 15 Cones * * * Contains: Oxyquinolin Benzoate, Boric Acid, Salicylic Acid, Lactic Acid, U. S. P. Coco Butter, White Wax * * * Prepared for Warner Renowned Medicine Co. Minneapolis, Minnesota" and "Warner Renowned Vaginal-Tablets Contains Oxyquinolin Sulphate, Lactic Acid, Boric Acid 15 Tablets * * * Prepared For Warner Renowned Medicine Co. Minneapolis, Minn."

LIBELED: 3–8–55, Dist. Minn.

CHARGE: 502 (a)—The statement on the box labels of the articles, when shipped, namely, "When desired for soothing action in minor vaginal irritation," was false and misleading since it represented and suggested that the articles were effective for self-treatment of pathological conditions of the vagina, and the articles were not effective for such purposes; and 502 (f) (1)—the labelings of the articles failed to bear adequate directions for use in the self-treatment of pathological conditions of the vagina, which was the purpose for which the articles were intended.

DISPOSITION: 5–10–55. Default—destruction.

4770. Atomotrone (or Vital-Tone) device. (F. D. C. Nos. 36884, 36885, 36886. S. Nos. 44–037 L, 44–056 L, 44–060 L.)

QUANTITY: 3 devices at Tulsa, Okla., in possession of B. R. Clements, Mrs. Melba Ferlin, and Mr. and Mrs. Robert F. Layman.

SHIPPED: Between 3–2–53 and 7–6–53, from Dallas, Tex., by Nick M. Faulkner.

ACCOMPANYING LABELING: The device in possession of B. R. Clements was accompanied by booklets entitled "Nature's Way of Health With The Vital-Tone Unit In Your Home" and "Suggested Instructions On Using Irradiated Water And Food."

RESULTS OF INVESTIGATION: The device consisted of a compartmented box containing an electrically operated "sun lamp" which was situated so that light emitted by the lamp might fall upon jugs of water placed in the box with several sheets of colored glass interposed between the lamp and the jugs. Water irradiated through blue- and purple-colored glass was designated "electric" or "E," and water irradiated through red- and amber-colored glass was designated "thermal" or "T."

The "electric" water, the "thermal" water, and a combination of the two were intended to be used in the cure, mitigation, and treatment of a great variety of diseases of man.

LIBELED: 7–26–54, N. Dist. Okla.

CHARGE: 502 (a)—when shipped, the labeling of the device in the possession of B. R. Clements contained false and misleading representations that the device was capable of providing an adequate and effective treatment for hemorrhoids, pain, inflammation, burns, cuts, sinus troubles, hay fever, colds, varicose veins, high blood pressure, infections, arthritis, asthma, ulcerated conditions, diseased tonsils, virus infection, infection of the bladder, colon, kidney, and blood, skin rash, heart conditions, low blood pressure, low glandular activity, constipation, cancer, and for providing vital energy in one's water and food; and 502 (f) (1)—the labeling of the remaining two devices, when shipped and while held for sale, failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: B. R. Clements, Mr. and Mrs. Robert F. Layman, and Mrs. Melba Ferlin, claimants, filed answers denying that the products were misbranded as alleged.

The case came on for trial before the court on 10–15–54, at which time the claimants announced that they did not wish to proceed with the trial and were withdrawing their answers. The court thereupon entered a decree condemning the devices and ordering them delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4771. Ergot of rye. (F. D. C. No. 37627. S. No. 11–883 M.)

QUANTITY: 80 112-lb. bags at Brooklyn, N. Y.

SHIPPED: 6–10–54, from Poland.

LIBELED: 2–2–55, E. Dist. N. Y.

CHARGE: 501 (a) (1)—contained insects while held for sale.

DISPOSITION: 3–18–55. Consent—claimed by Arnida Products Corp., New York, N. Y. Segregated, 257 lbs. destroyed.

4772. Rosebuds. (F. D. C. No. 37381. S. No. 12–401 M.)

QUANTITY: 231 lbs. in 5 drums and 11 49-lb. bags at New York, N. Y.

SHIPPED: 9–21–53, from North Bergen, N. J.

LIBELED: 12–1–54, S. Dist. N. Y.

CHARGE: 501 (a) (1)—contained insects while held for sale.

DISPOSITION: 12–30–54. Consent—claimed by Schieffelin & Co. Segregated, 433 lbs. denatured.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4773. Phenobarbital tablets, aspirin-phenobarbital tablets, and Obes-Ebb tablets. (F. D. C. No. 36678. S. Nos. 46–054 L, 46–062/3 L, 84–289 L.)

INFORMATION FILED: 1–13–55, S. Dist. N. Y., against Nyrope, Inc., New York, N. Y.

SHIPPED: Between 11–2–53 and 1–12–54, from New York to Massachusetts and Pennsylvania.

LABEL IN PART: (Btl.) "Tablets Phenobarbital ¼ [or "½"] grain," "Aspirin-Phenobarbital Tablets Each tablet contains * * * Phenobarbital . . . ¼ grain," and "No. 3 Tablets Obes-Ebb Each tablet contains: Amphetamine Sulphate 5 mgm."

CHARGE: 501 (c)—the strength of the articles when shipped differed from that which they purported or were represented to possess in that the *phenobarbital tablets* and the *aspirin-phenobarbital tablets* contained less phenobarbital and the *Obes-Ebb tablets* contained less amphetamine sulfate than declared on the label.

PLEA: Guilty.

DISPOSITION: 5–25–55. $500 fine.

4774. Rauwolfia serpentina (powder & tablets). (F. D. C. No. 37622. S. No. 5–484 M.)

QUANTITY: 1 drum containing 32 lbs. of powder, 175,000 tablets, each containing 100 mg. of powder, and 140,000 tablets, each containing 50 mg. of powder.

SHIPPED: 7–27–54, from New York, N. Y., by Prentiss Drug & Chemical Co.

LABEL IN PART: (Drum) "R. S. Root."

RESULTS OF INVESTIGATION: The article was invoiced as "Whole Rauwolfia Serpentina Root" and, after receipt by the consignee, it was dried and ground into a powder. A portion of the powder was used in the manufacture of tablets intended to be labeled in part "Each tablet contains Rauwolfia serpentina."

LIBELED: 1–25–55, E. Dist. Mich.

CHARGE: 501 (d) (2)—the article was represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part for the article when shipped; and 502 (i) (3)—the article was not *Rauwolfia serpentina*, and it was offered for sale under the name of another drug, namely *Rauwolfia serpentina*.

DISPOSITION: 3–31–55. Default—destruction.

4775. C-Tone. (F. D. C. No. 35362. S. No. 51–780 L.)

QUANTITY: 20 cartons, 12 8-oz. btls. each, at New York, N. Y.

SHIPPED: 6–22–53 and 6–24–53, from Englewood Cliffs, N. J., by Kegan Laboratories, Inc., through Byrne Products, Inc.

LABEL IN PART: (Btl.) "Rich in Activated Enzymes C-Tone The Natural Vitamin C Tonic * * * Four tablespoons furnish: *Natural* Vitamin C . . . 250 mg. MDR 8 * * * *Natural* Niacin . . . 0.08 mg. * * * Sole and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

ACCOMPANYING LABELING: Leaflets entitled "Which of These Dread Killers Threaten Your Advancing Years?" and display placards reading, in part, "Which Of These Conditions Threaten Your Advancing Years?" and "For That Pep of Health Natural C-Tone."

RESULTS OF INVESTIGATION: The leaflets and the placards described above had been printed by a New York firm for the distributor.

Analysis showed that the article contained less than 150 milligrams of vitamin C and less than 0.04 milligram of niacin per four tablespoons.

LIBELED: 7–27–53, S. Dist. N. Y.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Four tablespoons furnish: *Natural* Vitamin C _____ 250 mg. * * * *Natural* Niacin _____ 0.08 mg." was false and misleading; the label statements "Rich in Activated Enzymes" and "Vitamin C Tonic" were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of its enzyme content and was effective as a tonic, whereas it was not of such value because of its enzyme content and was not effective as a tonic; and the labeling of the article also contained false and misleading representations that the article was an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells, and was effective to provide energy and improve digestion.

DISPOSITION: Byrne Products, Inc., New York, N. Y., claimants, filed an answer denying that the article was adulterated or misbranded as alleged. Thereafter, the Government served interrogatories upon the claimant which were not answered; and, on 9–12–55, the court entered a default decree condemning the article and ordering its destruction.

4776. Chocolated Cokozole. (F. D. C. No. 37805. S. No. 5–869 M.)

QUANTITY: 94 1-pint btls, at Cincinnati, Ohio.

SHIPPED: Between the years 1943 and 1950, from New York, N. Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin B_1 (thiamine hydrochloride).

LIBELED: 3–7–55, S. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it purported and was represented to possess, namely, 10 milligrams of vitamin B_1; and 502 (a)—the label statement "Contains in One Fluid Ounce: * * * Thiamin Hydrochloride 10 Mg." was false and misleading.

DISPOSITION: 4–7–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4777. Diaplex. (Inj. No. 18.)

INFORMATION FOR CRIMINAL CONTEMPT FILED: On or about 4–24–52, Dist. Colo., against Henry Wayne Pierce, also known as Horace Wayne Pierce, and H. W. Pierce, Wellington, Colo.

CHARGE: The information alleged that the defendant, in a decree entered on 9–14–44, had been permanently enjoined from shipping in interstate commerce the weed, saltbush (*Atriplex canascens*), for sale under the name of "Diaplex," or under any label claiming the article *Diaplex* to be of therapeutic value in the treatment of diabetes (see drugs and devices notices of judgment, No. 725); that between 6–15–51 and 9–12–51, the defendant had shipped from Carr and Wellington, Colo., to Emmett, Idaho, Clarksdale, Mo., Brooklyn, N. Y., San Angelo, Tex., and Seattle, Wash., a quantity of saltbush, some of which was unlabeled and some of which was labeled "Diaplex for Diabetics," and that, by reason of these shipments of the article "Diaplex" which was offered in its label to be of therapeutic value in the treatment of diabetes and intended for use in the treatment of diabetes, the defendant was in contempt of the permanent injunction issued against him.

DISPOSITION: The defendant filed an answer, and on 12–8–54, the matter came on for hearing before the court without a jury. On 12–23–54, the court handed down the following findings and order:

BREITENSTEIN, *District Judge:* "This matter coming on for hearing this 8th day of December, 1954, upon motion of the United States for determination of the present mental condition of the defendant, and the United States being represented by James W. Heyer, Assistant United States Attorney for the District of Colorado, and the defendant being present and represented by his counsel, Phillip G. Dufford, Esquire, and the Court having heard the testimony and evidence presented and being fully advised in the premises, DOTH FIND:

"1. That the defendant Henry Wayne Pierce is now so mentally incompetent as to be unable to understand the nature of the proceedings against him or to assist in his own defense;

"2. That the mental condition of the defendant is not of a temporary nature such as would allow disposition of this matter under the provisions of Section 4246, Title 18 U. S. C.;

"3. That the permanent injunction issued against the defendant by this Court on the 14th day of September, 1944, remains operative and in full force and effect;

"4. That in view of the foregoing findings, the Court deeming it appropriate and necessary to order as follows, IT IS, THEREFORE,

"ORDERED, that the proceedings in the above-entitled case be dismissed, that the defendant be discharged from custody, and that the bond be exonerated and surety thereon discharged.

"IT IS FURTHER ORDERED that the Clerk of this Court shall prepare and the United States Marshal for the District of Colorado shall cause to be served, together with a certified copy of this order, upon the above-named defendant a certified copy of the writ of permanent injunction issued by this Court on September 14, 1944, which remains in full force and effect, and

"IT IS FURTHER ORDERED that if this defendant persists in further violations of the aforementioned writ of permanent injunction, upon notice thereof, the United States Attorney for the District of Colorado shall take appropriate action in the County in which defendant resides to have the defendant committed to a mental institution."

*See also Nos. 4763–4765, 4768–4770, 4775, 4776.

4778. Capon Springs water. (F. D. C. No. 10053. S. No. 45–453 F.)

QUANTITY: 5 cases, 1 5-gallon demijohn each; 9 cases, 6 ½-gallon btls. each; and 13 cases, 12 ½-gallon btls. each, at New York, N. Y.

SHIPPED: 3–16–43, from Philadelphia, Pa., and 3–18–43, from Capon Springs, W. Va., by Capon Water Co.

RESULTS OF INVESTIGATION: Examination showed that the article was ordinary potable water, containing per quart about two and one-half grains of mineral matter consisting largely of calcium bicarbonate, and that the water was therefore typical of the natural water in limestone regions.

LIBELED: 6–4–43, S. Dist. N. Y.

CHARGE: 502 (a)—certain statements on the bottle labels of the article when shipped were alleged to be false and misleading since such statements represented and suggested that the article, when consumed according to directions, would rebuild the body while cleansing it of waste matter, would exert an alkaline effect in the body and counteract acid conditions, would serve to restore improperly functioning kidneys and bowels to their normal activity, and would exert benefits to health greatly in excess of those derived from the consumption of ordinary drinking water, whereas the article when so consumed would not exert such effects nor produce effects essentially different from those produced by the consumption of similar quantities of ordinary drinking water.

DISPOSITION: Andrew P. St. Thomas, claimant, and the Capon Water Co., and Louis L. Austin and Virginia H. Austin, copartners, t/a Capon Springs & Farms, intervenors-claimants, filed an answer denying that the article was misbranded as alleged in the libel and filed an amended answer alleging the defense of res adjudicata.

The case came on for trial before the court without a jury on 3–7–44. The trial was concluded on 3–10–44, and the case was taken under advisement for consideration of the evidence and briefs of counsel. On 2–13–45, the court handed down the following opinion in favor of the dismissal of the libel:

CONGER, *District Judge:* "Libellant, the United States of America, seeks herein to confiscate a certain quantity of Capon Springs Water which it has seized.

"The libel states that this water, shipped in interstate commerce was misbranded in that, in violation of the Federal Food, Drug and Cosmetic Act (21 U. S. C. A. Sec. 352 (a)), the label on the bottles containing the water contained statements which were false and misleading.

"The following statements appearing on the labels are alleged to be false and misleading and to constitute misbranding:

> Rebuilds as it Cleanses * * *
>
> The Indians Called It Ca-Ca-Pa-On—"Health Water" * * *
> Known to physicians as alkaline, because it contains by nature those elements needed to counteract *acidity.*
>
> * * * beneficial in restoring the normal activity of the kidneys and bowels.
>
> Use according To A Natural Law of Health * * *
>
> For the best results * * * drink 2 glasses on rising, 2 more during the morning, 2 during the afternoon and 1 or 2 at night * * *

"The libel after alleging that these statements are false and misleading continues—'said articles when so consumed will not exert such effect nor produce effects essentially different from those produced by the consumption of similar quantities of ordinary drinking water.'

"The parties responsible for the bottling and shipment of the water have appeared and answered herein.

"The amended answer herein denies any misbranding.

"The fact that the waters were shipped in interstate commerce is not denied.

"The First and Second defense in the amended answer set up the defense of res adjudicata. These defenses concern two proceedings heretofore had in connection with Capon Springs Water. There can be no question but that the water involved in those proceedings is the same water with which we are concerned here.

"By these defenses, claimants allege that the truth of the statements on the label herein have been finally determined in the claimants' favor in two actions heretofore had and that said prior final decisions are res adjudicata determinative of the issues herein as to the truth or falsity of said statements.

"The second or later proceeding (second defense) was brought on or about March 3, 1936, before the Federal Trade Commission. The Respondents in that case were the same Respondents, their privies or predecessors in title now before this court.

"The proceeding was commenced pursuant to the provision of an Act of Congress creating a Federal Trade Commission (approved September 26, 1914) (15 U. S. C. A. Sec. 55 (a)). The gravamen of the complaint in that proceeding was that Respondents were guilty of falsely advertising their product in booklets, circulars and other written matter.

"The pertinent section of 15 U. S. C. A. Sec. 55 (a) reads as follows:

> The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect: * * *

"The precise charge is set forth in Paragraph Two and Paragraph Three of the libel. Paragraph Two in part reads as follows:

> Respondents, in the course and conduct of their business as aforesaid, distribute and circulate, among prospective purchasers of their said water, booklets, leaflets, circulars, and other written matter which contain many statements concerning the curative qualities of respondents' said water. Many of said statements are purportedly made by doctors and laymen, and the remainder by the respondents, in said booklets, leaflets, circulars, and other written matter, respondents falsely represent and imply that said water will cure, or is beneficial in the treatment of, many of the diseases, ailments, afflictions, and conditions which may be present or exist in the human body.
>
> Among the diseases, ailments, afflictions, and conditions named by the respondents in their said booklets, leaflets, circulars, and other written matter, so distributed and circulated among prospective purchasers of their said water, as diseases, ailments, afflictions, and conditions which their said water will cure, or is beneficial in the treatment of, are the following * * *. Then follows a long list of diseases too numerous to repeat, among which are kidney troubles, kidney pains, nephritis, bladder trouble, catarrhal affections of the stomach, hyperacidity, constipation, irregular bowels.

"Paragraph Three reads as follows:

> Respondents, in said booklets, leaflets, circulars, and other written matter, so distributed and circulated among prospective purchasers of their said water, falsely represent and imply that their said water acts "like magic"; "cures almost everything"; "aids digestion"; "restores energy"; is "beneficial to general health"; "keeps you fit"; "keeps you well"; that it has "eliminated tired feeling"; "maintains healthy digestive tract"; that it has "improved hearing"; is "indispensable to health"; "acts as a natural tonic"; "restores mental alertness and vigor"; "will help every living thing"; assures "All year round health and long life"; "supplies every one of the 16 elements in body"; and contains "valuable medicinal properties."
>
> In truth and in fact respondents' said water not only has not acted and does not act like magic, but has not acted and does not act at all on the human body in any different manner than does any pure potable water, nor does it contain any elements or medicinal properties in sufficient quantities to render it different from, or any of greater benefit than, any pure, potable water, and its use has not resulted and does not result in the benefits claimed for it by said respondents as above set out.

"The above allegations were put in issue by the answer of respondents. The issues were tried before a trial examiner, who made his report upon the facts to Federal Trade Commission, from which the Commission made its 'Findings as to the Facts and Conclusions.'

"A great deal of testimony was taken before the trial examiner. The real issue was as to the therapeutic value of this water. The Commission had as witnesses several chemists and three physicians. The conclusions of these experts was that this water had no special chemical value; that it had no therapeutic value; that it would not cure or benefit the specific diseases mentioned in the complaint; that the mineral content of this water was no greater than that of ordinary tap water; that this water would have no more effect than any good drinking water.

"Respondent put in testimony of four physicians who testified among other things that the water did possess therapeutic value and qualities; that it possessed therapeutic values different from other pure potable waters. Each testified that he prescribed this water in cases of illness and disease and told of the curative and beneficial effect by its use.

"There was taken in all about 600 pages of testimony.

"Some of the literature used by Respondent in advertising its product was put in evidence. It will not be necessary to go into the various claims made in these documents. However, a few extracts from one (Ex. 1) are pertinent. This is a small leaflet entitled 'Things You Will Observe About Capon Springs Water.' I quote some extracts therefrom:

REFRESHES

* * *

CLEANSES

* * *

5. It has prompt action on the kidneys. Capon cleanses your blood of acid and toxic poisons.

REBUILDS

6. It regulates the bowels. Capon restores their normal peristaltic action (the eliminative urge).

7. It acts as a natural tonic. Capon supplies every one of the sixteen elements in your body.

* * *

WHY THE INDIANS CALLED IT CA-CA-PA-ON—"HEALING WATERS"

* * *

Capon water is known to physicians as alkaline * * *

"These are extracts from one of the pamphlets which the Commission based its charge of false advertising. The label which is under fire here was put in evidence.

"The trial examiner in his Findings has set forth most of the statements thereon under the heading: 'Respondent's Representations, Concerning the Efficiency of Capon Water.'

"Notwithstanding the broadness of the charges and the plethora of evidence, the Commission simply contented itself with a finding against Respondent, 'that the use of Capon Water *alone* either externally or internally will not cure kidney troubles'. . . . (Then follows the long list of diseases which the Commission claims Respondent advertised Capon Water would cure or be beneficial in the treatment thereof.).

"This was the only respect in which the Commission found that Respondent by its advertising had violated the provision of the Federal Trade Commission Act. As a result thereof an order was made by the Commission that Respondent in connection with the offer for sale and distribution of its water cease and desist from representing directly or by implication 'that the use of the said water alone, either externally or internally will cure kidney troubles. . . .' etc. This record indicates that this order was complied with.

"It should be noted that the testimony taken before the Commission was of the same nature as that before me. Most of it was by experts (doctors and chemists). It all had to do with the chemical properties and therapeutic value of this water. The experts' testimony taken before the Commission might very well have been substituted for and used in the case before me.

"The order of the Federal Trade Commission was affirmed by the United States Circuit Court of Appeals for the Third Circuit (*Capon Water Co., et al. v. Federal Trade Commission, 107 Fed. (2) 516*).

"I have gone at some length into this proceeding before the Federal Trade Commission because I am of the opinion that it is the real serious defense to the issue here.

"I have come to the conclusion that the decision of the Federal Trade Commission binds the Libellant here.

"In the proceeding before the Commission the litigated question was the chemical and therapeutic value of this water. The Commission had before it the printed material advertising Capon Water. In it were many and rather extravagant statements extolling the virtue and healing property of the water which included the claim that the consumption of this water would cure or be beneficial in the treatment of most of the ills and sickness that men and women are afflicted with.

"Yet, after a lengthy trial the Commission simply placed its condemnation upon the claim that *this water alone would cure.*

"It gave its approval, by a failure to condemn all the other claims which included those mentioned in Exhibit 1, and heretofore set forth.

"I referred to those statements particularly because they are identical with or approximate the statements on the label which the Government contends are false and misleading—'in that said statements represent and suggest that the article of drug when consumed according to directions will rebuild the body while cleansing it of waste matter, will exert an alkaline effect in the body and counteract acid conditions, will serve to restore improperly functioning kidneys and bowels to their normal activity and will exert benefits to health greatly in excess of those derived from the consumption of ordinary drinking water.' . . . (Paragraph V of the Libel).

"This is exactly the issue that was tried before the Commission and decided by it as I have pointed out above.

"The Government contends that proceedings before the Commission are not a bar to the successful prosecution of this action, because the label was not passed on by the Commission. I think it is correct that the label with the statements thereon was not specifically passed on. However, may it be said that certain statements in the pamphlets may be used and are not false and misleading while the same statements used on the label may not be used and are false and misleading. I think not.

"As I see it the underlying issue in this action and in the proceeding before the Commission is the same. That being so, the adjudication in the proceeding before the Commission is determinative of the issue here. *United States v. Willard Tablet Co., 141 F. (2) 141; George H. Lee Co. v. Federal Trade Commission, 113 F. (2) 583.*

"The fact that in one proceeding we have the Federal Trade Commission as the complainant and in this case we have the United States of America does not alter the situation, neither does the fact that different remedies are sought in each proceeding affect the result. *United States v. Willard Tablet Co., supra. George H. Lee Co. v. Federal Trade Commission, supra.*

"My opinion is fortified by another adjudication as to this same water. *United States v. Ninety-Four Dozen, more or less, Half-Gallon Bottles Capon Springs Water, 48 F. (2) 378.* This adjudication is alleged as res adjudicata to this action and is the first defense in the amended answer herein.

"In that proceeding the United States of America by a libel sought to condemn 94 cases more or less, half-gallon bottles of Capon Springs Water. The prosecution was based on the Food and Drug Act (21 U. S. C. A. 1 et seq.).

"This action was tried in the United States Eastern District of Pennsylvania. The complaint in that case was that there was a misbranding on the label. In his opinion Judge Dickinson, who tried the case, set forth the charge as follows:

> It is charged that Capon Springs Water is marketed under a label which describes it to be "Healing Water," thereby implying that the drinking of it will have curative and therapeutic results, when in fact the water is more accurately described as drinking water, having only the properties of what might be called ordinary spring water.

"The label which was objected to was in form as follows:

Capon Springs Water known to the Catauaba Indians as "Ca-Ca-Pa-On" Healing Water.

2 Quarts Net—Bottled at the Springs. [Then follows an analysis in type too small to be conveniently read.]

Natural Mineral Spring Water Famous for Two Centuries. Capon Water Co., Capon Springs, W. Va.

"Judge Dickinson in his opinion stated, 'We see nothing in the label in this case which would justify a finding that it was fraudulent.' In that action the libel was dismissed. Affirmed by the Circuit Court of Appeals for the Third Circuit, 51 F. (2) 913.

"If the adjudication in this case is not determinative of the entire issue here it is at least determinative of the charge of misbranding as applied to the phrase on the label 'The Indians called it Ca-Ca-Pa-On Health Water.' The fact that in this one case have the words '*Healing Water*' and in the other '*Health Water*' has no significance. The words are synonymous.

"For the reasons which I have given above, I find that the libel should be dismissed.

"Settle decree on notice."

Pursuant to the above opinion, the court, on 7–5–45, entered a decree directing the dismissal of the libel and the return to the claimant of the article seized. A stay of execution of the decree was obtained by the Government, and an appeal was taken by the Government to the Court of Appeals for the Second Circuit. On 7–17–46, the following decision was handed down by that court:

Augustus N. Hand, *Circuit Judge:* "This is a libel *in rem* brought under the Food, Drug and Cosmetic Act based upon the alleged misbranding of 'Capon Springs Water.' The District Court dismissed the libel upon defenses of *res judicata* based upon two prior proceedings. The 'Capon Springs Water' was alleged to be misbranded because of the following statement which appears on the bottle labels:

Rebuilds as it Cleanses * * *
The Indians Called it Ca-Ca-Pa-On "Health Water" * * *
Known to physicians as alkaline, because it contains by nature those elements needed to counteract *acidity.*
* * * beneficial in restoring the normal activity of the kidneys and bowels.
Use According To A Natural Law of Health * * *
For the best results * * * drink 2 glasses on rising, 2 more during the morning, 2 during the afternoon and 1 or 2 at night * * *.

"The foregoing statements are said to be false and misleading because they represent that the article when consumed according to directions will rebuild the body while cleansing it of waste matter, will exert an alkaline effect on the body by counteracting acid condition, will serve to restore improperly functioning kidneys and bowels to their normal activity, and will exert benefits to health greatly in excess of those derived from the consumption of ordinary drinking water.

"In the former suit by the United States brought in the District Court for the Eastern District of Pennsylvania in 1928, 'Capon Springs Water' was alleged to have been misbranded and was sought to be forfeited under the then terms of the Food and Drugs Act, which at that time required as a condition of any misbranding which would cause forfeiture of the articles therefor that the packages or labels containing them should bear a statement regarding the curative or therapeutic effects of the article 'which is false and fraudulent.' 21 U. S. C. § 10. But under the amended Food and Drug Act, 21 U. S. C. § 352, which governs the present litigation, a drug or device is deemed misbranded '(a) if its labelling is false or misleading in any particular.' In other words, the amended act dispenses with the necessity of proving fraud in the misbranding so that the prior adjudication in *United States* v. *94 Dozen, more or less, bottles Capon Springs Water,* 48 F. 2d 378, aff'd 51 F. 2d 913 (CCA. 3), to the effect that there was no fraud in the branding was not a bar to the present pro-

ceeding, since the court was not there required to make any finding that the statements were misleading if no fraud was proved and it made none. As the causes of action in that proceeding and in this are not the same, there is no *res judicata* and, as none of the present issues were determined in the prior proceeding, there is no estoppel.

"In 1936 the Federal Trade Commission filed a complaint against Capon Water Company and Louis L. Austin, claimants herein, charging them with falsely advertising 'Capon Springs Water' as curing or aiding in the treatment of many diseases and introduced as evidence of misbranding the label from which we have quoted beginning with the words: 'Rebuilds as it cleanses * * *' The Commission by its findings of January 20, 1938, determined that the claimants represented in their advertising that 'Capon Springs Water' *alone* would cure the various diseases and ailments mentioned, whereas in fact the use of that water *alone* would not have such an effect, and the acts of the claimants therefore had a tendency to and did 'mislead and deceive the purchasing public and caused them erroneously to believe that the use of said water alone will cure the various diseases * * *.' The Commission accordingly ordered the Capon Water Company, Capon Springs Mineral Water, Inc., and Louis L. Austin to cease and desist from representing that the use of the water alone would cure the various diseases mentioned. The court below treated this order as equivalent to an approval of forms of advertising which did not represent that 'Capon Springs Water' *alone* would cure or relieve the ills referred to. The court's interpretation of the prior order is unwarranted. We cannot understand how a failure to make any finding except that the use of 'Capon Springs Water' *alone* would not have curative effects can be the equivalent of a finding that the water had the curative effects when not used alone. For this reason there was no estoppel against the United States in the assertion of its general claims in the present libel. Clearly the decision in the prior proceeding was not *res judicata* since it was founded upon a different claim from that asserted in the case of bar. There can be no basis for the contention that the finding of the Commission that the claimants falsely represented that the use of 'Capon Springs Water' *alone* would cure diseases should indirectly operate in their favor though they are the very parties against whom the former decision was rendered. Even if the decision had any relevance here it should operate as an estoppel against the claimants *pro tanto* rather than in their favor. Under any possible theory the former decision of the Commission that the representation was misleading that the use of 'Capon Springs Water' *alone* would cure the various diseases was a finding of an ultimate fact which under *The Evergreens* v. *Nunan*, 141 F. 2d 927 (CCA. 2) could not be used as a 'mediate datum' in the present proceeding.

"In *George H. Lee Co.* v. *Federal Trade Commission*, 113 F. 2d 583 (CCA. 8), and *United States* v. *Willard Tablet Co.*, 141 F. 2d 141 (CCA. 7), it was held that an estoppel by judgment existed against the United States and the Federal Trade Commission in respect to findings of fact rendered in a prior proceeding which were in favor of the defendant. But in the case at bar no findings in favor of the claimants were made in the prior proceeding. They are here attempting to use the findings formerly rendered in favor of the United States for their benefit. The reason for such a contention we cannot comprehend.

"It is unnecessary for us to discuss here the contention of the plaintiff that, irrespective of any general rules of *res judicata* or estoppel by judgment, the Commission had a right to change its decision, for we have shown above that no such rules could be applicable under the facts disclosed in the record.

"The suggestion of the claimants that because under § 45 (l) of the Federal Trade Commission Act they are made subject to a penalty for a violation of a cease and desist order, that remedy is exclusive and a forfeiture proceeding under the Food, Drug and Cosmetic Act will not lie, is unwarranted. The remedies are plainly cumulative and not exclusive.

"The order is reversed and the cause is remanded with directions to proceed in accordance with the views expressed in this opinion."

Following the remanding of the case to the United States District Court for the Southern District of New York, an order was entered with the agreement of the parties directing the removal of the case to the United States District Court for the District of New Jersey for retrial. Thereafter, it was discovered

that the article under seizure had disappeared, thus rendering the libel action moot. Accordingly, an order was entered by the court on 12–3–54, dismissing the libel.

4779. Medicinal herb teas. (F. D. C. No. 37338. S. Nos. 82–922/30 L.)

QUANTITY: 37 6-oz. pkgs. of *Formula No. 1*, 1 20-lb. drum and 5 6-oz. pkgs. of *Formula No. 2*, 175 lbs. in drums and 23 6-oz. pkgs. of *Formula No. 3*, 5 5-oz. pkgs. of *Formula No. 4*, 1 30-lb. drum and 10 5-oz. pkgs. of *Formula No. 5*, 1 20-lb. drum and 15 6-oz pkgs. of *Formula No. 9*, 6 6-oz pkgs. of *Formula No. 6*, 1 100-lb. drum of *Formula No. 7*, 1 20-lb. drum and 23 7-oz. pkgs. of *Formula No. 8*, at Chicago, Ill., in the possession of Father Francis' Herbs.

SHIPPED: From Jersey City and North Bergen, N. J. The *Formula No. 9* was shipped prior to 9–21–53, and the other articles were shipped between 1–14–54 and 8–30–54.

LABEL IN PART: (Pkg.) "Medicinal Herb Tea Formula No. 1 A Laxative Mixture * * * Active Ingredients: Senna, Buckthorn, And also contains: Johnswort, Woodruff, Juniper, Peppermint, Knotgrass [or "Formula No. 2 A mildly alkaline Stomachic Mixture Contains: Boldo, Dandelion, Buckthorn, Johnswort, Juniper, Knotgrass, Life Everlasting," "Formula No. 3 A mildly alterative, alkaline Stomachic Mixture * * * Contains: Horsetail, Johnswort, Myrtle, Huckleberry, Raspberry, Strawberry, Goat's Rue, Nettle, Linden, Bean, Dog Grass, Elecampane," "Formula No. 4 A mild herbal beverage Mixture * * * Contains: Knotweed, Parsley, Java Tea, Birch, Blue Century, Bearberry," "Formula No. 5 For Coughs due to Colds & relief of minor Throat irritations * * * Contains: Mullein, Sage, Iceland Moss, Comfrey, Anise, Ginseng," "Formula No. 6 A mildly alkaline, alterative Herbal Mixture * * * Contains: Buckthorn, Knotgrass, Elder, Misletoe, Coriander, Horsetail, Ginseng," or "Formula No. 8 A mildly alkaline, alterative Herbal Mixture * * * Contains: Buckthorn, Bladderwrack, Goldenrod, Mistletoe, Sundew, Knotgrass, Star Anise,"]," "Aromatic Bath Herbs Formula No. 9 For Refreshing Bath & Steam Bath * * * Contains: Bladderwrack, Rosemary, Rose Buds, Lemon Verbena, Orris, Thyme, Lavender, Peppermint, Sage." (drum) "Cut & Sifted Formula #7 For #775 * * * Containing The Following Passion Flower Herb White Willow Bark Hawthorne Berries Sweet Orange Peel."

ACCOMPANYING LABELING: Leaflets entitled "From NATURE'S Own LABORATORY . . . 'NATURE—The Best DOCTOR'."

RESULTS OF INVESTIGATION: The "*Formula No. 7*" was intended to be repackaged into 6-ounce packages and relabeled by the consignee as "Medicinal Herb Tea Formula No. 7." The other articles in the packages described above were repackaged from bulk shipments and relabeled by the consignee. The above-mentioned leaflets were printed locally for the consignee and distributed to prospective customers.

LIBELED: 11–3–54, N. Dist. Ill.

CHARGE: 502 (a)—the accompanying labeling of the articles (bulk and repackaged material) while held for sale contained false and misleading representations that the articles were effective in the treatment of the following conditions: (Formula No. 1) Conditions affecting the stomach and intestines, indigestion, hyperacidity, poisonous conditions of the intestines, colic, nausea, bloating, torpidity, headache, and insomnia; (Formula No. 2) Liver and gallbladder troubles, impaired digestion, and impure intestinal tract; (Formula No.

3) Diabetes; (Formula No. 4) Kidney and bladder troubles, rheumatism, arthritis, internal pains, nervousness, sleeplessness, backache, swelling of ankles, puffiness under the eyes, loss of energy, loss of appetite, and lowered resistance against disease; (Formula No. 5) Bronchitis, sore throat, fever, and for preventing colds; (Formula No. 6) Rheumatism, gout, arthritis, neuritis, sciatica, lumbago, and muscular chill; (Formula No. 7) Nervousness, sleeplessness, weakened nerves, dizziness, heart trouble, palpitations of the heart, and breathlessness; (Formula No. 8) Obesity and overweight troubles; and (Formula No. 9) Impaired circulation of the blood, impure skin, impaired metabolism, and impaired health.

DISPOSITION: 2–23–55. Default—destruction.

4780. Various drugs. (F. D. C. No. 37710. S. Nos. 9–163/71 M.)

QUANTITY: 1 2,200-tablet bag and 21 100-tablet btls. of *Formula No. 247*, 46 100-tablet btls. of *Formula No. 125*, 41 100-tablet btls. of *Formula No. 162*, 42 100-tablet btls. of *Formula No. 9*, 32 100-tablet btls. of *Formula No. 84*, 15 100-tablet btls. of *Formula No. 262*, 13 100-tablet btls. of *Formula No. 75*, 52 10-oz. btls. of *Formula No. 275*, and 108 6-oz. btls. of *Scalp-Aid*, at Los Angeles, Calif., in the possession of Science Associates.

SHIPPED: Between 9–16–54 and 1–5–55, from Quitman, Ark., and Detroit, Mich.

LABEL IN PART: (Bag) "Gland-Food Tablets No. 247";

(btl.) "'Dr. Nature' Brand Health Products Formula No. 247 100 Tablets Gland-O-Tone Tablets * * * Ingredients: Sarsaparilla, Muira Puama, Damiana, Gentian, Hawthorne, Valerina, Boneset, Excipients [or "Formula No. 125 100 tablets Liver–Aid Tablets An deobstruent and tonic to the Liver * * * Ingredients: Agrimony, Oak, Uva Ursi, Mandrake, Gentian, Chicory, Poplar, Fennel, Excipients," "Formula No. 162 100 Tablets Kidney–Aid Tablets A Diuretic and Tonic to the Kidneys and Bladder * * * Ingredients: Juniper, Broom, Clevers, Nettle, Poplar, W. Pine, Bladderwrack, Plantain, Excipients," "Formula No. 9 100 Tablets Arthru Tablets Vegetable Anodyne and Tonic in Arthritic disorders * * * Ingredients: Ava Kava, Birch, Papaya, Nettle, Quassia, W. Yam, Willow, Poplar, Excipients," "Formula No. 84 100-Tablets Nerv-O-Tone Tablets * * * Ingredients: Valerian, Vervain, Cinchona, Hops, Squills, Mistletoe, Cola, Mint, Dill, Excipients," "Formula No. 262 100 Tablets General Tonic Tablets * * * Ingredients: Saccharum O, Corn and Wheat Protein, Extract Molderlin, Excipients," "Formula No. 75 100 Tablets Lank–&–Lean Tablets * * * Ingredients: Sassafras, Bladderwrack, Nettle, Burdock, Fennel, Cleavers, Yell. Dock, White Ash, Excipients," "Formula No. 275 10 Fluid Ozs. General Tonic Syrup * * * Ingredients: Herbal Extracts of Medicago Sativa, Alfalfa, Lespedeza, Buffalo Herb, Luzerne, Prairie Herb, Saccharum O," and "Rx–2 Scalp-Aid * * * Active Ingredients: Soponated Creosols, Acacacia [sic], Linseed, Bay and other Aromatic Oils. Contents 6 Oz. Less than 2% Alcohol"]."

ACCOMPANYING LABELING: Booklets entitled "New Health Products * * * Catalog."

RESULTS OF INVESTIGATION: The articles in the bottles, after their shipment in interstate commerce, were relabeled by the consignee. The booklets were printed locally for the consignee.

LIBELED: On or about 3–17–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling of the articles while held for sale contained the following false and misleading representations:

1. That the *Formula No. 247* was effective to revitalize the system, aid the glands, tissues, and organs to function more efficiently, help replace lost energies, and to supply necessary nutritional materials for normal gland function and balance;

2. That the *Formula No. 125* was effective to deobstruct and tonic the liver and to promote better bile flow, thereby producing a healthy liver which would prevent biliousness, sallow complexion, constipation, dark brown taste, bad breath, and impaired digestion;

3. That the *Formula No. 162* was effective as a diuretic and tonic to the kidneys and bladder, to soothe the bladder preventing getting up nights, to relieve minor irritability of the bladder, and give welcome relief to backache and puffy eyes;

4. That the *Formula No. 9* was effective as an anodyne and tonic in arthritic disorders and was effective to relieve the agonizing pains of rheumatism, neuralgia, lumbago, and neuritis;

5. That the *Formula No. 84* was effective to relieve nerve tensions, make the nerves stronger, the mind clearer, fresher, and more calm, promote healthful sleep, rest, and relaxation, restore "vim and vigor," and help one relax and accomplish more;

6. That the *Formula No. 262* was effective as a general tonic and useful as an aid in restoring and maintaining the kind of health that makes life worth living, and that it was an aid in all rundown and convalescent conditions, loss of strength, lowered vitality, sluggish blood, faulty assimilation, excess gas, fermentation, and anemia;

7. That the *Formula No. 75* was effective in treating obesity;

8. That the *Formula No. 275* was effective as a general tonic, a marvelous blood builder, and was valuable in rundown, convalescent conditions, poor circulation, nonassimilation of foods, chronic tiredness, impure blood, gas from stomach and bowels, and to help in cleansing the blood stream;

9. That the *Scalp-Aid* was an adequate and effective treatment for falling hair, itching scalp, dandruff, drab lifeless hair, and to stop most scalp troubles.

DISPOSITION: 4–7–55. Default—destruction.

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PRODUCTS

[1] (4770, 4775) Seizure contested.
[2] (4764) Injunction issued.
[3] (4778) Seizure contested. Contains opinions of the courts.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4770, 4775) Seizure contested.
[2] (4764) Injunction issued.
[3] (4778) Seizure contested. Contains opinions of the courts.
[4] (4777) Contempt of injunction. Contains findings and order of the court.

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U. S. GOVERNMENT PRINTING OFFICE: 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4781–4800

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial, or which were dismissed after trial; and (2) criminal proceedings which were terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *individual* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *November 6, 1956.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 4787, 4791; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4787.

403512—56——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4781-4800

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article in one case was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," and in another case the label of the article bore the caution statement as quoted above, but the article was not one to which Section 503 (b) (1) applies.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

4781. Mannitrau tablets and Serpenitrite tablets. (F. D. C. No. 37638. S. Nos. 4-317/8 M.)

QUANTITY: 1 34,000-tablet drum and 36 1,000-tablet btls. of *Mannitrau tablets* and 1 28,000-tablet drum of *Serpenitrite tablets* at Rochester, N. Y., in possession of William A. Straub.

SHIPPED: 12-7-54 and 12-16-54, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Drum) "Special Formula * * * 'Mannitrau' * * * Each Tablet Contains: Phenobarbital 15 mg. * * * Mannitol Hex. 30 mg. Rauwolfia 50 mg. Rutin 20 mg. Caution: For Manufacturing, Processing or Repacking in the preparation of a new drug limited by Federal law to investigational use. * * * Richlyn Laboratories Philadelphia, Pa."; (btl.) "Mannitrau Mannitol Hexanitrate 30 mg. Rauwolfia Serpentina 50 mg. Rutin 20 mg. Phenobarbital 15 mg. * * * Use only as directed by a physician. Distributed by William A. Straub Rochester 9, New York"; (drum) "Special Formula * * * Each Tablet Contains: Rauwolfia Serpentina Pwd. Root 50 mg. Pwd. Extract Hyoscyamus 15 mg. Sodium Nitrite 50 mg. Pheno-

barbital 10 mg. Caution: For Manufacturing, Processing or Repacking in the preparation of a new drug limited by Federal law to investigational use. * * * Richlyn Laboratories Philadelphia, Pa."

RESULTS OF INVESTIGATION: The *Mannitrau tablets* in the bottles had been repackaged from the bulk drum and relabeled by the consignee. The *Serpenitrite tablets* were intended by the consignee to be repackaged into bottles labeled, in part, "Serpenitrite Rauwolfia Serpent. Po. Rt. 50 mg. Hyoscyamus Pwd. Extract 15 mg. Sodium Nitrite 50 mg. Phenobarbital 10 mg. * * * Use only as directed by a physician. Distributed by William A. Straub Rochester 9, New York."

Neither the Richlyn Laboratories nor William A. Straub had an effective new-drug application for the *Mannitrau tablets* or the *Serpenitrite tablets*.

LIBELED: 2–2–55, W. Dist. N. Y.

CHARGE: 505 (a)—the articles were new drugs within the meaning of the law, and no applications filed pursuant to the law were effective with respect to the articles.

DISPOSITION: 10–28–55. Default—destruction.

4782. Jel Royale tablets. (F. D. C. No. 38229. S. No. 9–550 M.)

QUANTITY: 24 100-tablet btls. and 7 500-tablet btls. at Los Angeles, Calif.

SHIPPED: 4–9–55, from San Antonio, Tex., by Howard Harmon.

LABEL IN PART: (Btl.) "Jel Royale Each Tablet Contains 0.5 mg. Queens' Jelly."

ACCOMPANYING LABELING: Brochures entitled "Is This your Fountain of Youth?"

RESULTS OF INVESTIGATION: The brochures were printed locally in Los Angeles, Calif.

LIBELED: 7–27–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article was effective to delay age, restore sexual vigor, and promote growth; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–18–55. Default—destruction.

4783. Honey with Royal Jelly. (F. D. C. No. 38237. S. Nos. 9–553/4 M.)

QUANTITY: 12 cases, 24 12-oz. btls. each, at Los Angeles, Calif., in possession of Halco Corp.

SHIPPED: 4–28–55, from Weslaco, Tex., by Ault Bee Farms.

LABEL IN PART: (Btl.) "100% Pure Bee Ripened Honey * * * Fortified With 57.6 [or "5.76"] Grains Of That Wonder Food Queen's Royal Jelly and 5% Powdered Milk Recommended tablespoon [or "teaspoon"] daily."

ACCOMPANYING LABELING: Circulars entitled "The Queen's Jelly" and "On Honey, Royal Jelly and Natural Foods" and brochures entitled "The Story of 'Royal Jelly' and Peter."

LIBELED: 7–27–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article when shipped and while held for sale contained false and misleading representations that the

article was effective as a natural remedy for growth, reproduction, rejuvenation, and longevity, as a specific for otherwise incurable maladies, to relieve women during the menopause, to restore normality to the growth of retarded children, to produce a general well-being, to prevent fatigue from prolonged intellectual work, to stimulate the appetite, to stimulate all bodily functions, to cure heart patients, to alleviate suffering from nervous and vascular disorders, to cure Parkinson's disease, and to cure cancer in chickens and prolong the life of pigs, rats, and guinea pigs; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–15–55. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4784. Penicillin sodium salt. (F. D. C. No. 37010. S. No. 63–084 L.)

QUANTITY: 190 vials at Decatur, Ill.

SHIPPED: On an unknown date, from Brooklyn, N. Y.

LABEL IN PART: (Vial) "200,000 Oxford Units Penicillin (Sodium Salt) * * * Expiration Date: August – 1947 087040–B."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the labeled potency of penicillin sodium.

LIBELED: 7–20–54, S. Dist. Ill.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, penicillin sodium, the name of which is recognized in the United States Pharmacopeia, an official compendium, and while held for sale its strength differed from the standard set forth in the compendium; 502 (a)—the label statement "200,000 Oxford Units Penicillin (Sodium Salt)" was false and misleading as applied to a product which contained less than the labeled potency; and 502 (l)—the drug purported to be and was represented as a drug composed partly of a kind of penicillin, and it was from a batch with respect to which a certificate or release, as required by regulations, was not in effect.

DISPOSITION: Lincoln Laboratories, Inc., claimant, filed an answer averring that the article was not misbranded while held for sale after shipment in interstate commerce as alleged in the libel, but was held by the claimant for investigational and research purposes only. Subsequently, written interrogatories served upon the claimant by the Government were answered.

The case came on for trial before the court without a jury on 12–6–55, and on 12–16–55, the court, having found that the claimant and the Government had agreed that the product should be destroyed, ordered that the product be released to the claimant for destruction. On 1–5–56, the court entered an order dismissing the libel with prejudice on the grounds that, since the subject matter thereof had been destroyed, all questions in the case had become moot.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4785. Whole pituitary tablets. (F. D. C. No. 36371. S. No. 60–144 L.)

QUANTITY: 104,200 tablets in 2 drums at Atlanta, Ga.

SHIPPED: 11–20–53, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Drum) "Special Tablets Enteric SC Brown Code C.D.A.T. Lot No.: 8996 Formula contains at time of manufacture: Whole Pituitary Po 3 gr. per tablet."

LIBELED: 2–3–54, N. Dist. Ga.; libel amended 3–16–54.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use; and 503 (b) (4)—the article was not a drug subject to 503 (b) (1), and prior to dispensing, its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Crews Drug Co., Inc., Atlanta, Ga., claimant, filed an answer denying that the article was misbranded as alleged and claiming that the article was exempt from the requirements of 502 (f) (1) under the provisions of 503 (b) (2) since it was to be dispensed only upon the prescription of a physician. Thereafter, on 3–16–54, the Government filed a motion to strike that portion of the claimant's answer claiming an exemption for the article, and in support of such motion, it claimed that the defense relied upon was insufficient in law. A motion was filed also to amend the libel to include the charge of misbranding within the meaning of 503 (b) (4). The motion to amend the libel was granted on 3–16–54.

The claimant filed a motion to amend its answer to include the claim that the article was also exempt from the labeling requirements of the Act by reason of the provisions of 503 (b) (1) (B). The motion was granted on 4–20–54. On 9–20–54, the Government's motion to strike was granted, there being no objection on the part of the claimant.

Subsequently, interrogatories were served upon the claimant by the Government and were answered. On 12–7–55, the court, upon motion of the Government and with the consent of the claimant, entered a decree condemning the article and ordering its destruction.

4786. Apiol and ergotin compound. (F. D. C. No. 38176. S. No. 21–585 M.)

QUANTITY: 17 pkgs., 24 24-capsule boxes each, at Philadelphia, Pa.

SHIPPED: 4–1–54, from Brooklyn, N. Y., by Jamco Co.

LABEL IN PART: (Box) "Penhurst Apiol and Ergotin Compound 24 * * * Each capsule contains: Apiol 5 Min. Oil Pennyroyal 1/2 Min. Ergotin 4 Gr. Aloin 1/8 Gr. Vegetable Oil O. S. 10 Min."

LIBELED: 6–2–55, E. Dist. Pa.

CHARGE: 503 (b) (4)—the article was a drug subject to 503 (b) (1), and when shipped its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8–3–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4787. Quinine hydrochloride. (F. D. C. No. 33786. S. No. 49–431 L.)

INDICTMENT RETURNED: 12–20–54, S. Dist. N. Y., against Sidney J. Cohen, New York, N. Y.

ALLEGED VIOLATION: The indictment alleged that, on or about 8–25–52, while a quantity of *quinine hydrochloride* was being held for sale, the defendant mutilated, destroyed, and removed a portion of the labeling displayed upon the drum containing the article, which acts resulted in the article being misbranded.

CHARGE: 502 (b) (1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502 (e) (1)—the article failed to bear a label containing the common or usual name of the

*See also No. 4785.

article; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

Disposition: The defendant entered a plea of not guilty on 1–13–55, and the case came on for trial before a jury on 6–27–55. On 6–28–55, after presentation of the Government's evidence, the defendant changed his plea to guilty, and on 7–8–55, was sentenced to 8 months in prison and fined $250.

4788. Rutinfusion. (F. D. C. No. 37900. S. No. 11–836 M.)

Quantity: 1 50-lb. drum at East Paterson, N. J., in possession of Merit Food Co., Inc.

Shipped: 1–1–55, from Station Yard, Wokingham, Berkshire, England, by Rutin Products, Ltd.

Accompanying Labeling: Leaflets designated "Rutinfusion makes 'Life as on a Summer's Day' " and "Rutinfusion (Technical Information)" and a number of printed package labels, the front panel bearing the statement "Merit rutinfusion * * * Sole Distributor Merit Food Co., Inc. 890 River Drive East Paterson, N. J. Weight 2 Oz. Net" and the back panel bearing the statement "Rutin is described as being non-toxic * * * Rutinfusion is specially grown and processed leaves and flowers of the buckwheat plant."

Results of Investigation: The package labels and leaflets were prepared locally for the consignee and were intended for use by the consignee as labeling for the article in 2-ounce packages for distribution for retail sale.

Libeled: 3–23–55, Dist. N. J.

Charge: 502 (a)—the labeling of the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for overcoming capillary fragility; maintaining and restoring normal capillary strength; overcoming hypertension; preventing vascular accidents such as paralytic strokes; maintaining normal capillary strength for persons receiving medical treatment with thiocyanate drugs, salicylate drugs, and arsenical drugs; controlling pulmonary hemorrhage; overcoming internal bleeding; reducing the feeling of strain and fatigue after heavy or prolonged effort; strengthening the tiny blood vessels of the brain and body so that they may resist the effect of atomic fission; overcoming bodily failure after middle age; preventing premature decay; overcoming paralytic strokes caused by high blood pressure, eye conditions due to high blood pressure, and all forms of weakness of the circulatory system; preventing apoplexy and retinal hemorrhage; overcoming gastric hemorrhage and bleeding from the gums; preventing or delaying the advent of any ailments associated with age; strengthening and toning up the whole circulatory system, leaving the blood vessels vigorous and elastic; and for the treatment of asthma; and 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use for the purposes for which it was intended.

Disposition: 4–27–55. Default—destruction.

4789. Mineral oil. (F. D. C. No. 37582. S. Nos. 7–803/4 M.)

Quantity: 2,300 gallons in 1 tank, at Oklahoma City, Okla., in possession of Roisman Products Co.

Shipped: 12–15–54, from Whiting, Ind.

Accompanying Labeling: Loose bottle labels bearing the following printed matter: "American Mineral Oil U. S. P. Heavy Contents 1 Pint Kent Directions Dose: One teaspoonful to one tablespoonful 2 or 3 times daily, or

one or two tablespoonfuls upon retiring. Soothing and safe for adults and children Kent Laboratories Oklahoma City, Okla."

LIBELED: 1–11–55, W. Dist. Okla.; amended 1–18–55.

CHARGE: 502 (a)—the statement on the bottle labels of the article, while held for sale, namely, "Dose: One teaspoonful to one tablespoonful 2 or 3 times daily * * * Soothing and safe for adults and children" was false and misleading since the statement represented and suggested that the article was safe and suitable for use in the manner recommended when such was not the case; and 502 (f) (2)—the labeling of the article failed to warn that the article should not be taken at any time other than at bedtime and should not be administered to infants except on the advice of a physician.

DISPOSITION: 2–8–55. Consent—claimed by Roisman Products Co. and relabeled.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4790. Dextro-amphetamine sulfate capsules. (F. D. C. No. 37965. S. No. 21–807 M.)

QUANTITY: 4 bottles at Philadelphia, Pa.

SHIPPED: 10–26–54, from Franklin Square, Long Island, N. Y., by Carl H. Kaplan, t/a Economy Buying Service, Inc.

LABEL IN PART: (Bottle) "250 Capsules Dextro Amphetamine Sulfate Each Capsule Contains 15 Mg. of Dextro Amphetamine Sulfate."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 15 percent of the declared amount of dextro-amphetamine sulfate.

LIBELED: 5–3–55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported and was represented to possess, namely, 15 milligrams of dextro-amphetamine sulfate per capsule; and 502 (a)—the label statement "Each Capsule Contains 15 Mg. of Dextro Amphetamine Sulfate" was false and misleading.

DISPOSITION: 7–27–55. Default—destruction.

4791. Neulate capsules. (F. D. C. No. 38058. S. No. 2–001 M.)

QUANTITY: 102 btls. at Roanoke, Va.

SHIPPED: 9–23–54, from Baltimore, Md., by Carroll Chemical Co.

LABEL IN PART: (Btl.) "Neulate Capsules 100 Each Capsule Contains: 2-(2-Dimethylamino-Ethyl)-2-Thenylamino) Pyridine-Hcl. 50 Mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 80 percent of the declared amount of 2-(2-Dimethylamino-Ethyl)-2-Thenylamino) Pyridine-Hcl.

LIBELED: 5–26–55, W. Dist. Va.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported and was represented to possess, namely, 50 milligrams of 2-(2-Dimethylamino-Ethyl)-2-Thenylamino) Pyridine-Hcl. per capsule; and 502 (e) (1)—the label of the article failed to bear the common or usual name of the article, methapyrilene hydrochloride.

DISPOSITION: 6–15–55. Default—destruction.

*See also No. 4784.

4792. Ipecac root. (F. D. C. No. 38051. S. No. 6–873 M.)

QUANTITY: 105 lbs. in 2 drums at Salt Lake City, Utah.

SHIPPED: 3–8–55, from New York, N. Y., by Smith Crude Drug & Spice Co.

LIBELED: 5–24–55, Dist. Utah.

CHARGE: 501 (d) (2)—the article was represented as *ipecac root*, and a substance other than ipecac root had been substituted in whole or in part for the article.

DISPOSITION: 7–29–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4793. Diabena. (F. D. C. No. 34916. S. No. 57–490 L.)

QUANTITY: 795 16-fl. oz. btls. and 3 5-gal. btls. at Richmond, Va., in possession of Mrs. W. B. Wood, Jr., t/a C. D. Walker Co.

SHIPPED: On 8–25–50, during November 1950, and on unknown dates, from New York, N. Y.

LABEL IN PART: (Btl.) "Diabena – Alcohol 12½% Active Ingredients Tephrosiavirginiana, Lithii Citras, Cinnamon, Food Coloring. Dose: Two teaspoonfuls every four hours in water. Children in proportion to age. C. D. Walker Co. P. O. Box 1203 Richmond 9, Virginia."

ACCOMPANYING LABELING: Leaflets entitled "Diabena."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and, upon its receipt by the consignee, a portion was relabeled and repackaged into the bottles.

LIBELED: 3–25–53; amended 4–15–53, E. Dist. Va.

CHARGE: 502 (a)—the labeling of the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for diabetes.

DISPOSITION: Mrs. W. B. Wood, Jr., claimant, filed an answer denying that the article was misbranded as alleged. On 5–8–53, the Government served interrogatories upon the claimant, who filed objections thereto with the court on 5–15–53. The court, after consideration of arguments of counsel, sustained the claimant's objections on 5–27–53. Subsequently, the Government filed a request for admissions to which the claimant objected. The claimant's objections were upheld in part. The case was tried before the court on 9–9–54, and on 3–23–55, the court handed down findings of fact and conclusions of law, holding, in effect, that the Government failed to prove by a preponderance of the evidence that the labeling claims were false and misleading.

The Government filed a notice of appeal to the United States Court of Appeals for the Fourth Circuit; and, on 11–7–55, after consideration of argument and briefs of counsel, the following opinion was handed down by that court:

DOBIE, *Circuit Judge:* "This case arose on a libel of information filed in the Eastern District of Virginia, under Section 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 334 (a), praying seizure and condemnation of an article of drug known as 'Diabena.' The libel alleged that the drug had been shipped in interstate commerce; that certain descriptive literature became associated with it after its interstate shipment; and that it was misbranded and subject to condemnation because this accompanying labeling falsely represented that the drug would be effective in the treatment of diabetes (21 U. S. C. 352(a)).

"After the seizure, Mrs. W. B. Wood, Jr., appeared as claimant and filed an

*See also Nos. 4782–4784, 4788–4790.

answer admitting all of the essential allegations of the libel, except that the labeling statements were false or misleading. The case was tried by the District Judge without a jury. The sole question was that of the efficacy of 'Diabena' in the treatment of diabetes.

"The critical findings of the District Judge were:

> 10. The Government failed to prove by a preponderance of the evidence its charges that the labeling claims are false and misleading. Its experimental evidence consisted only of animal studies, in which the drug failed to reduce the blood sugar in some of the test rabbits; it had no clinical experiments in which the drug was tested on man. Instead, it relied on the opinions of a medical doctor and a pharmacologist who stated the drug would not prevent, cure, or mitigate diabetes but further stated that they were not familiar with the drug nor had they ever tested or used it, and that insulin, which 'Diabena' does not contain, is the best remedy for the disease known to medical science at the present time.
>
> 11. Without the results of actual use of the drug on patients with diabetes, I am unable to find that the Government has proved its case.
>
> 12. In order to show that the drug is not effective as claimed to be, it must be proved that the drug was given to patients in accordance with its directions and at different levels of dosage, in order to give it a fair trial.

"The Government has appealed to us from the District Judge's order dismissing the libel. We think the order of the District Court is clearly erroneous and must, therefore, be reversed.

"Claimant called no witnesses to testify that 'Diabena' is effective in the treatment of diabetes. See, United States v. 50 etc. bottles of Sulfa-Seb, 54 F. Supp. 759, 763. There was stipulated into the record the affidavit of Dr. Thompson and statements of clinical records (which had been filed with the patent papers) which indicated that 'Diabena' had been effective in the treatment of certain diabetics. These seem to have impressed the District Judge, though he expressly stated: 'My opinion is based upon the lack of evidence on the part of the Government to show that it ("Diabena") is not effective.' It is clear that the granting of the patent gives no right of misrepresentation, but it merely restrains others from manufacturing, using or selling what is covered by the patent. Decker v. Federal Trade Commission, 176 F. (2d) 461, 463, cert. denied 338 U. S. 878.

"It is well settled that seizures under the Federal Food, Drug and Cosmetic Act are civil in nature. The Government need prove its case only by a preponderance of the evidence. United States v. 5 Cases, 'Figlia Mia Brand' Vegetable Oils, 179 F. (2d) 519, cert. denied 339 U. S. 963; C. C. Company v. United States, 147 F. (2d) 820.

"To show that 'Diabena' is worthless in the treatment of diabetes, the Government introduced three expert witnesses, who testified at some length. The qualifications and competence of these witnesses was not open to question.

"Dr. Henry St. George Tucker, Jr., is a practising physician and an Associate Professor of Medicine at the Medical College of Virginia, who has specialized in the treatment of diabetes. In no uncertain terms, he testified that the only means of keeping diabetes under control are the reduction of carbohydrates in the diet and the injection of insulin; that, in spite of many attempts, no successful oral treatment of diabetes has ever been found. He further stated that in his opinion, which was the consensus of modern medical opinion, a drug containing the ingredients of 'Diabena' would have no value whatever in the treatment of diabetes, and that these ingredients have been totally discarded in the treatment of diabetes.

"Dr. Haag is Professor of Pharmacology at the Medical College of Virginia. His specialty has been the study of drugs and their therapeutic uses in connection with the human body. Dr. Haag said that in his opinion, based upon his training and experience as a pharmacologist, an article having the ingredients of 'Diabena' would have no effect in the treatment of diabetes or the lowering of blood sugar. He then described the known effects and uses for the ingredients of 'Diabena.' The principal ingredients of 'Diabena' are Tephrosia Virginiana (also known as Devil's Shoestring, Wild Sweetpea and Goat's Rue), lithic citras, cinnamon and food coloring. Tephrosia, he said, is a vermifuge (a product used to expel worms from the gastrointestinal tract) and tends to increase sweating; lithium citrate has no medical use; cinnamon is merely a flavoring.

On cross-examination, Dr. Haag admitted that he had not administered 'Diabena' to any patients.

"The final witness for the Government was Dr. Robert L. Grant, a pharmacologist employed by the Food and Drug Administration, who since 1941 has been engaged in testing the action of insulin and other drugs which might affect the level of blood sugar. He testified about experiments which he conducted with 'Diabena' by administering it to rabbits, the official test animal for insulin in the United States Pharmacopoeia. He stated that the tests on 'Diabena' were the best he could devise and were the same as those conducted to determine the effectiveness of insulin or any other drug to show its effect on diabetes or the lowering of blood sugar. Dr. Grant explained that a drug which would reduce the level of blood sugar in rabbits would reduce the level of blood sugar in human beings; and that the results of his tests showed that 'Diabena' had no more effect on the lowering of blood sugar than did water.

"The applicable law of this case has been rather clearly set out in two leading cases. In United States v. One Device Intended for Use as a Colonic Irrigator, 160 F. (2d) 194, 199, Circuit Judge Huxman stated:

> That these medical experts were competent and qualified to testify as to the matter in issue is clear. They were not disqualified merely because they had not seen it in operation. They testified not only that they were conversant with colonic irrigation, but also that they were familiar with the principles of the particular device in question. * * * Being fully conversant with the principles of colonic irrigation and with the principles upon which this device operated, the testimony of these medical experts was competent and constituted substantial evidence.

And in Neff v. Federal Trade Commission, 117 F. (2d) 495, 497, Circuit Judge Soper (speaking for our Court) said:

> The actual question now presented is whether the testimony of the six experts who testified for the Commission can be considered substantial evidence in view of their lack of actual experience in the use of the petitioner's preparation, as compared with the conflicting statements of doctors who had administered Glantex to their patients. We think the evidence is sufficient to support the Commission's finding. All of the experts were well qualified to speak upon the subject; and their opinions, though based only upon their general medical and pharmacological knowledge, constituted substantial evidence tending to show that the representations of the petitioner were not justified.

"In Wigmore on Evidence, Vol. III, page 3, Section 687, we find:

> To deny the competency of a physician who does not know his facts from personal observation alone is to reject medical testimony almost in its entirety. To allow any physician to testify who claims to know solely by personal experience is to appropriate the witness-stand to impostors. Medical science is a mass of transmitted and collated data from numerous quarters; the generalizations which are the result of one man's personal observation exclusively are the least acceptable of all. The law must recognize the methods of medical science. It cannot stultify itself by establishing, for judicial inquiries, a rule never considered necessary by the medical profession itself. It is enough for a physician, testifying to a medical fact, that he is by training and occupation a physician; whether his source of information for that particular fact is in part or entirely the hearsay of his fellow-practitioners and investigators, is immaterial.

"See, also, Irwin v. Federal Trade Commission, 143 F. (2d) 316; John J. Fulton Co. v. Federal Trade Commission, 130 F. (2d) 85, cert. denied 317 U. S. 679; Dr. W. B. Caldwell, Inc. v. Federal Trade Commission, 111 F. (2d) 889.

"As to the consensus of present-day medical opinion as a fact, see, United States v. Kaadt, 171 F. (2d) 600; Research Laboratories, Inc. v. United States, 167 F. (2d) 410, cert. denied 335 U. S. 843. Experiments with animals have been held to be valid in showing the physiological effects of drugs on human beings, United States v. Lesser, 66 F. (2d) 612.

"Finally, we observe that it might indeed be difficult to find a diabetic who would act as a guinea-pig by abandoning insulin over any substantial period of time and submitting to treatment by 'Diabena' or any other drug whose efficiency has not been established. Diabetes is a serious disease which, if not properly and promptly treated, tends to become increasingly dangerous. Indeed, Dr. Tucker unhesitatingly testified that if a person suffering from diabetes is deprived of insulin, serious consequences might well follow.

"We think the Government has clearly established its case by a preponderance of the evidence. The judgment of the District Court is, accordingly, reversed and the case is remanded to that court with instructions to enter judgment in favor of the United States."

The case was remanded to the United States District Court for the Eastern District of Virginia; and, on 3–22–56, the court ordered the product destroyed.

4794. Reclu capsules. (F. D. C. No. 37111. S. No. 40–270 L.)

QUANTITY: 12 100-capsule btls. at Phoenix, Ariz.

SHIPPED: 7–28–54 and 9–4–54, from Fullerton, Calif., by Reclu Co.

LABEL IN PART: (Btl.) "Reclu Caps Each Capsule Contains Approx. 0.58 Grams Of A Specially Prepared Concentrate Made From Fresh Cabbage, Dessicated At Low Temp. * * * Reclu's Cabbage Concentrate Diet for Peptic Ulcers."

LIBELED: 9–30–54, Dist. Ariz.

CHARGE: 502 (a)—the bottle label of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for peptic ulcers.

DISPOSITION: 11–24–54. Default—destruction.

4795. Trumac tablets. (F. D. C. No. 36865. S. No. 90–431 L.)

QUANTITY: 10 cases, 12 btls. each, at Kansas City, Kans.

SHIPPED: 5–11–54, from Detroit, Mich., by Cemac Laboratories, Inc.

LABEL IN PART: (Btl.) "100 Tablets Trumac Tablets Enteric Coated Improved For the palliative relief of pain (headache) associated with Sinus Conditions, Facial Neuralgia, and Simple Headache. Contains: Salicylamide, as the active ingredient; with a catalytic agent CS 210 in a specially prepared base."

ACCOMPANYING LABELING: A flier designated "SINUS? . . . get palliative relief with TRUMAC TABLETS"; a leaflet designated "Are You A SINUS Victim?"; and placards designated "Are You a Sinus Victim? Ask About The New Tablet Treatment TRUMAC TABLETS"; and "TRUMAC TABLETS For the Palliative Relief of Pain Associated with Sinus Conditions."

LIBELED: 7–8–54, Dist. Kans.

CHARGE: 502 (a)—when the article was shipped, its bottle label and accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for sinus conditions.

DISPOSITION: 10–12–54. Default—destruction.

4796. Artritina tablets. (F. D. C. No. 37298. S. No. 40–268 L.)

QUANTITY: 48 100-tablet btls. at Phoenix, Ariz.

SHIPPED: 2–11–54, from Los Angeles, Calif., by Los Angeles Pharmacal Co.

LABEL IN PART: (Btl.) "Artritina For the relief of symptoms of Arthritis, Rheumatism & Neuritis Each tablet contains: Salicylamide. . . . 3.0 grs. Calcium Succinate. . . . 2.8 grs. Thiamine Chloride. . . . 1.0 mg. Para Aminobenzoic Acid. . . . 10.0 mg."

LIBELED: 10–22–54, Dist. Ariz.

CHARGE: 502 (a)—the label of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, and neuritis, and that it was effective for overcoming all of the symptoms and signs of such conditions.

DISPOSITION: 2–14–55. Default—destruction.

4797. Anterior pituitary extract and ovarian extract. (F. D. C. No. 37591. S. Nos. 8–500/1 L.)

QUANTITY: 24 30-cc. vials of *anterior pituitary extract* and 30 30-cc. vials of *ovarian extract* at Syracuse, N. Y.

SHIPPED: 10–20–53 and 12–11–53, from Philadelphia, Pa., by Addison Laboratories.

LABEL IN PART: (Vial) "Multiple Dose Vial Anterior Pituitary Extract Each cc. contains the soluble water extract of 18.5 grains of fresh anterior pituitary glands. Intramuscularly or Subcutaneously * * * in severe functional hemorrhage," and "Multiple-Dose Vial Ovarian Extract * * * Intramuscular * * * Each cc. contains: Ovarian Extract 40 gr. Chlorobutanol 0.5% * * * in the treatment of functional menstrual irregularities, climacteric symptoms and related conditions."

LIBELED: 1–11–55, N. Dist. N. Y.

CHARGE: 502 (a)—the labels of the articles contained false and misleading representations that the *anterior pituitary extract* was effective in the treatment of functional hemorrhage and that the *ovarian extract* was effective in the treatment of functional menstrual irregularities, climacteric symptoms, and related conditions.

DISPOSITION: 3–2–55. Default—destruction.

4798. Glanfime. (F. D. C. No. 37043. S. No. 58–694 L.)

QUANTITY: 317 cartoned vials at Detroit, Mich.

SHIPPED: 2–12–54, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: (Vial) "30 cc. * * * Glanfime Intramuscular Only * * * Indications: Non-Specific Protein Therapy. To be used as an appetite depressant in the treatment of obesity."

LIBELED: 8–10–54, E. Dist. Mich.

CHARGE: 502 (a)—the statement on the vial label of the article when shipped "Indications: Non-Specific Protein Therapy" was false and misleading since the statement represented and suggested that the article was effective, upon injection, to cause a foreign protein reaction, which was contrary to fact; and 502 (a)—the name "Glanfime" and the statements on the vial label "Each 2 cc. represents the water soluble extraction of dried glands derived from: * * * Suprarenal Cortex, fresh gland ____ 3.0 grs. Thyroid U. S. P. ____ 2.0 grs. Pituitary Anterior, fresh gland ____ 1.0 grs. Pituitary Posterior, fresh gland ____ 0.1 grs. Ovarian Substance, fresh gland ____ 15.0 grs. Thymus, fresh gland ____ 3.0 grs. Lymphatic, fresh gland ____ 3.0 grs." were false and misleading since such name and statements represented and suggested that the declared glandular extracts

were active ingredients, whereas such glandular extracts possessed no therapeutic activity and, therefore, would not be effective either as appetite depressants in the treatment of obesity or for nonspecific protein therapy.

DISPOSITION: 10–22–54. Default—destruction.

4799. Antibiotic lozenges. (F. D. C. No. 37645. S. Nos. 18–081/87 M.)

QUANTITY: 29 shipping cartons containing a total of 237,300 tablets, 175 display cartons, each containing 20 retail cartons, and a number of empty retail and display cartons at New York, N. Y., in possession of Thompson Medical Co., Inc.

SHIPPED: Between 12–20–54 and 1–4–55, from Newark, N. J.

LABEL IN PART: (Retail carton) "Thompson Throataid Antibiotic Lozenges Fast Throat Relief Formula: Tyrothricin 1 mg. Benzocaine 5 mg. Cetyl Dimethyl Benzyl, Amonium Chloride 1 mg. Benzyl Alcohol 1:500 Pleasantly Flavored. 15 Lozenges Fast pain relief for sore throats due to colds, irritations, excessive smoking or speaking. Recommended for mouth and gum irritations and after tooth extractions * * * Distributed By Thompson Medical Company Inc. New York 1, N. Y."

ACCOMPANYING LABELING: Window streamers headed "Sore Throat * * * Thompson Throataid."

RESULTS OF INVESTIGATION: The article was shipped from Newark, N. J., in a number of shipping cartons and, after its receipt by the consignee, a portion of the article was repacked into the retail cartons. The retail cartons then were packed into the display cartons. The retail cartons, display cartons, and window streamers were printed for the consignee by printers located in New York, N. Y.

LIBELED: 2–9–55, S. Dist. N. Y.

CHARGE: 502 (a)—the labeling of the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for sore throat.

DISPOSITION: 2–16–55. Consent—claimed by Thompson Medical Co., Inc., and relabeled.

4800. Mary Mac Relax-O-Motor Massage Cushion. (F. D. C. No. 37974. S. Nos. 7–827/8 M.)

QUANTITY: 9 devices at Oklahoma City, Okla.

SHIPPED: During July 1954 and on 4–13–55 and 5–4–55, from Dallas, Tex., by McDaniel Mfg. Co.

ACCOMPANYING LABELING: Leaflets entitled "Here's New Mary Mac Relax O Motor Electric Mechanical Cushion," "Here's The Easy Way! New Mary Mac Relax O Motor Electric Mechanical Cushion," and "Mary Mac * * * Relax-O-Motor Amazing Deep Penetrating Motorized Massage," and post cards entitled "Miracle Mary Mac Relax-O-Motor Massage Cushion."

RESULTS OF INVESTIGATION: The device was a box with cushioned surfaces. It contained an electric motor which imparted a mechanical vibration to the cushioned surfaces when attached to household electric current.

LIBELED: 5–17–55, W. Dist. Okla.

CHARGE: 502 (a)—the labeling accompanying the device when shipped contained false and misleading representations that the device would aid digestion, improve blood circulation and elimination, relieve arthritis, asthma, varicose veins,

neuritis, and congestion, improve physical fitness, give the body new life and vigor, put pep into the body, and give the body pickup.

DISPOSITION: 1–20–56. Default—delivered to the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4781 TO 4800

PRODUCTS

[1] (4793) Seizure contested. Contains opinion of the court.
[2] (4784, 4785) Seizure contested.
[3] (4787) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4793) Seizure contested. Contains opinion of the court.
[2] (4784, 4785) Seizure contested.
[3] (4787) Prosecution contested.

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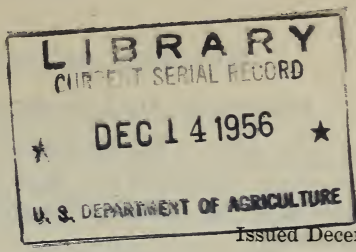

D. D. N. J., F. D. C. 4801–4840 Issued December 1956

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4801–4840

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *November 27, 1956.*

CONTENTS

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4801. (F. D. C. No. 37838. S. Nos. 65–798/9 L.)

INFORMATION FILED: 5–17–55, E. Dist. Mich., against **John A. Guarnieri (partner of and pharmacist for Guarnieri Pharmacy), Detroit, Mich., and Owen A. Hoyt (pharmacist).**

CHARGE: Between 10–13–54 and 10–15–54, *penicillin G potassium tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1–17–56. Guarnieri was fined $500 and Hoyt $50.

4802. (F. D. C. No. 37855. S. Nos. 65–795 L, 65–840 L.)

INFORMATION FILED: 5–17–55, E. Dist. Mich., against **Harry Berlin, t/a Berlin Drug Co., Detroit, Mich., and Albert A. Frumin (pharmacist).**

CHARGE: Between 10–13–54 and 10–18–54, *penicillin potassium tablets* and *methyltestosterone tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Berlin to dispensing *penicillin potassium tablets* and by Frumin to dispensing *methyltestosterone tablets.*

DISPOSITION: 12–19–55. Berlin—$400 fine; Frumin—$200 fine.

4803. (F. D. C. No. 37240. S. Nos. 45–786 L, 45–895/6 L, 45–901 L.)

INFORMATION FILED: 6–21–55, Dist. Mass., against **Samuel Theodore Cohen, t/a Harbor Village Pharmacy, South Boston, Mass.**

CHARGE: Betweeen 11–13–53 and 1–5–54, *penicillin G potassium tablets* were dispensed 3 times without a prescription and *amphetamine sulfate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 11–2–55. $400 fine.

4804. (F. D. C. No. 36670. S. Nos. 64–286 L, 64–288 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against **Hewitt's Drug Store, Inc., Anchorage, Alaska, Francis C. Bowden (president), and D. Carl Leonard and Dennis A. Short (pharmacists).**

CHARGE: Between 8–28–53 and 8–31–53, *penicillin G potassium tablets* were dispensed twice without a prescription.

PLEA: Guilty—by corporation and Francis C. Bowden and D. Carl Leonard to count 1 of the information and by Dennis A. Short to the remaining count.

DISPOSITION: 6–24–55. Corporation fined $350 and each individual $50.

4805. (F. D. C. No. 36667. S. Nos. 75–861 L, 75–863 L, 75–867 L, 75–869 L, 75–872 L, 75–881 L, 75–883 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against **Bert's Drug Stores, Inc., t/a Bert's Spenard Drugs, at Spenard, Alaska, and as Bert's Fifth Avenue Pharmacy, Bert's Payless Drug, and Bert's Drug Store, at Anchorage, Alaska; and against Arthur W. Burston (president of the corporation), and Donald L. Haldiman, Ellsworth M. West, John W. Shy, William Luopa, Orrin D. Clark, and William F. Rodgers (pharmacists).**

CHARGE: Between 8–28–53 and 9–3–53, *penicillin G potassium tablets, chloramphenicol capsules,* and *chlortetracycline capsules* were each dispensed once and *procaine penicillin G* was dispensed 3 times without a prescription, and

secobarbital sodium capsules were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by corporation and Arthur W. Burston to dispensing *penicillin G potassium capsules;* by Donald L. Haldiman to dispensing *chloramphenicol capsules;* by Ellsworth M. West to dispensing *chlortetracycline capsules;* by John W. Shy to dispensing *secobarbital sodium capsules;* and by each of the other three defendants to dispensing *procaine penicillin G* once.

DISPOSITION: 6–24–55. $350 fine against corporation and $50 fine against each individual.

4806. (F. D. C. No. 37854. S. Nos. 12–083/4 M, 12–311/12 M, 12–324 M.)

INFORMATION FILED: 7–27–55, S. Dist. N. Y., against **Louis R. Pena, t/a Pena Pharmacy, New York, N. Y.**

CHARGE: Between 1–3–55 and 1–10–55, *A-P-Cillin tablets* were dispensed twice and *Dexedrine Sulfate tablets, Gantrisin tablets,* and *Dexedrine Spansule capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8–3–55. $250 fine.

4807. (F. D. C. No. 37845. S. Nos. 65–791/2 L, 65–835 L.)

INFORMATION FILED: 5–17–55, E. Dist. Mich., against **Thomas T. Matthews, t/a Matthews Cut Rate Drugs, Detroit, Mich., and William Curtis Ford (pharmacist), and Charles A. Moss (clerk).**

CHARGE: Between 10–8–54 and 10–16–54, *penicillin G potassium tablets* were dispensed twice and *methyltestosterone tablets* were dispensed once without a prescription.

PLEA: Guilty—by Matthews and Moss to dispensing *penicillin G potassium tablets* and by Ford to dispensing *methyltestosterone tablets.*

DISPOSITION: 12–20–55 and 12–22–55. Ford and Moss each fined $150 and Matthews $500.

4808. (F. D. C. No. 36668. S. No. 64–262 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against **Joseph Kelly Boy (a pharmacist for Seeley's Drug Store), Anchorage, Alaska.**

CHARGE: On 8–27–53, *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–24–55. $50 fine.

4809. (F. D. C. No. 37833. S. Nos. 89–297 L, 89–305/7 L.)

INFORMATION FILED: 4–11–55, W. Dist. Ark., against **Brown G. Appleton, t/a Appleton's Drug Store, Warren, Ark., and Robert I. Gray (a pharmacist).**

CHARGE: Between 8–24–54 and 10–13–54, *penicillin G potassium tablets* and *thyroid tablets* were each dispensed once without a prescription, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 6–2–55. Each defendant placed on probation for 1 year.

4810. (F. D. C. No. 37844. S. Nos. 61–000 L, 68–686 L.)

INFORMATION FILED: 6–16–55, E. Dist. N. Y., against **Mandel Herold, t/a Mayfair Drug Co., Brooklyn, N. Y.**

CHARGE: On 9–3–54, *Benzedrine Sulfate tablets* and *phenylbutazone tablets* were each dispensed once without a prescription.

DISPOSITION: On 6–30–55, the defendant entered a plea of not guilty. Thereafter the defendant filed a motion to suppress the evidence obtained during the inspection of his establishment, on the grounds that it was obtained by an illegal search and seizure, and to dismiss the information.

The motion came on for hearing before the court on 11–7–55; and, on 1–10–56, after consideration of testimony and arguments and memoranda of counsel, the court denied the defendant's motion, handing down the following opinion:

BRUCHHAUSEN, *District Judge:* "The defendant, Mandel Herold, makes this motion under Rule 41 of the Federal Rules of Criminal Procedure for an order suppressing evidence claimed to have been illegally procured and for incidental relief.

"The information, filed against the defendants, Mandel Herold, proprietor of a drug store known as the Mayfair Drug Company, and Alexander Braaf, his pharmacist (now deceased), charged that they dispensed drugs without a prescription in violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. 331 (k), hereinafter referred to as the Food and Drug Act.

"Pursuant to Section 704 (a) of that Act (21 U. S. C. A. 374 (a)), two inspectors of the Food and Drug Administration entered the drug store and presented the proprietor with a notice of inspection. That section permits authorized government officers to enter places where commodities embraced by the Act may be found and to inspect those places and commodities, after giving notice.

"In connection with the inspection, the agents examined and copied prescription files, charge accounts, refill books and invoices of purchase and sale. Another section of the Act, 21 U. S. C. A. 373, permits the inspectors to have access to copy documents, provided, however, that evidence, obtained pursuant to the said Section 373 shall not be used in a criminal prosecution of the person from whom it is obtained.

"The defendant Herold by this motion seeks to suppress the evidence contained in these documents and to dismiss the information filed herein as having been obtained in violation of his Constitutional guarantees against unlawful search and seizure, contained in the Fourth and Fifth Amendments, and having been used in violation of them as well as in violation of Section 703 of the Food and Drug Act (21 U. S. C. A. 373, supra) granting immunity from prosecution.

"The defendant's first contention is that the inspection of the premises was improper, in that Section 704 (a) under which it was conducted (21 U. S. C. A. 374 (a)) applies, by its very title, to factories and warehouses. The comprehensiveness of the statute itself (which includes vehicles) and some of the recent cases construing it indicate that a drug store that satisfies the other requirements of the statute qualifies for inspection. U. S. v. Arnold's Pharmacy Inc., D. C. N. J. 1953, 116 F. Supp. 310; United States v. Lyon Drug Co., E. D. Wisc., 1954, 122 F. Supp 597.

"The defendant maintains, however, that the inspection and the copying of the records should only have been conducted after a notice was served under Section 703 of the Act (21 U. S. C. A. 373) which would have given him the aforesaid immunity from prosecution. Several recent cases held that records may be examined and copied by government agents conducting an inspection under Section 704 without the necessity of resorting to the procedure of Section 703 or being bound by the provisions thereof, if permission to inspect the records is given by an authorized person. U. S. v. Crescent-Kelvan Co., 3 Cir., 1948, 164 F. 2d 582; U. S. v. 75 Cases, etc., 4 Cir., 1944, 146 F. 2d 124; U. S. v. Scientific Aids Co., D. C. N. J., 1954, 117 F. Supp. 588; U. S. v. Lyon Drug Co., supra; U. S. v. Arnold's Pharmacy, Inc., supra.

"The defendant further argues that permission to examine and copy the records was not voluntarily given and that he firmly protested against those acts. The government does not deny that evidence obtained by an illegal search and seizure may not be used in a prosecution, but asserts that the evidence in question was procured not only with the consent, but even with the

cooperation of the defendant. The papers submitted by both sides on this point are irreconcilable, but the quality and quantity of the government's affidavits and the documents, consisting of receipts and affidavits executed by the defendant himself, as well as several witnesses, as opposed to the sole, self-serving affidavit of the defendant as well as the absence of the corroborating affidavit of his former attorney, present at the time in question, demonstrate the strength of the government's position.

"The Court, however, is reluctant to determine the question presented, without affording the parties the opportunity of a trial of the issue before this Court, without a jury, at which time the witnesses may testify and be subjected to cross-examination. The authorities support this procedure, where the Constitutional right of immunity from unlawful search and seizure is involved. Such trial should be had, prior to the trial of the action, pursuant to Rule 41 (e) of the Federal Rules of Criminal Procedure."

Thereafter, the defendant changed his plea to guilty; and, on 3–13–56, he was fined $1,500.

4811. (F. D. C. No. 35612. S. Nos. 85–983/4 L, 88–580 L.)

INFORMATION FILED: 3–21–55, Dist. S. Dak., against **Independent Drug Store, a partnership, Sioux Falls, S. Dak., and William Trimble (manager).**

CHARGE: Between 5–19–54 and 6–30–54, *Benzedrine Sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–25–55. Each defendant fined $150.

4812. (F. D. C. No. 37219. S. Nos. 40–416 L, 40–419 L, 40–421 L.)

INFORMATION FILED: 7–18–55, S. Dist. Calif., against **Royal Drug Co., Inc., Los Angeles, Calif., Alvin C. Weiss (president of the corporation), Joseph P. Shure (a pharmacist), and Jack Silberman (a clerk employed by the corporation).**

CHARGE: Between 2–16–54 and 5–19–54, *Dexedrine Sulfate tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by each defendant to dispensing the tablets once.

DISPOSITION: 9–6–55. Corporation and Weiss each fined $1,000; Shure and Silberman each fined $200. Each individual also given sentence of 1 year in jail, which was suspended, and placed on probation for 6 months.

4813. (F. D. C. No. 37271. S. Nos. 90–094/5 L, 90–098 L.)

INFORMATION FILED: 8–19–55, W. Dist. Mo., against **Amin Boutros (a physician), Kansas City, Mo.**

CHARGE: Between 7–8–54 and 7–9–54, *dextro-amphetamine sulfate tablets* were dispensed twice and *secobarbital sodium capsules* were dispensed once without a prescription.

DISPOSITION: On 9–9–55, the defendant filed a motion to dismiss the information on the grounds that it failed to state facts sufficient to constitute an offense and that it attempted to charge the defendant, a duly licensed practitioner of medicine, with a violation of the Federal Food, Drug, and Cosmetic Act, which Act was not applicable to the defendant.

The court overruled the defendant's motion on 9–27–55. On 12–23–55, the defendant entered a plea of nolo contendere and was fined $3,000, plus costs, and was placed on probation for 3 years.

4814. (F. D. C. No. 37841. S. Nos. 68–758 L, 68–761 L.)

INFORMATION FILED: 6–14–55, E. Dist. N. Y., against **David G. Wald, t/a Wald Prescription Pharmacy, Brooklyn, N. Y., and Alvin Konigsberg (pharmacist).**

CHARGE: Between 9–15–54 and 10–1–54, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription and once upon a request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by Wald to counts 1 and 2 and by Konigsberg to count 2.

DISPOSITION: 10–20–55. Wald fined $1,000 and Konigsberg $100.

4815. (F. D. C. No. 37263. S. Nos. 60–366 L, 60–590 L, 60–596 L, 60–669 L, 60–874 L, 60–882 L, 60–888 L.)

INFORMATION FILED: 9–7–55, W. Dist. S. C., against **Ernest D. Harrell, Jr., t/a Harrell Drug Co., Greenville, S. C., and William T. Edens (a pharmacist).**

CHARGE: Between 4–7–54 and 9–27–54, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription and 4 times upon requests for prescription refills without authorization by the prescriber, and *secobarbital sodium capsules* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by Harrell to all 7 counts of information and by Edens to counts 2, 4, 5, 6, and 7.

DISPOSITION: 10–24–55. Harrell fined $250 and Edens $25.

4816. (F. D. C. No. 37241. S. Nos. 89–384 L, 89–746 L.)

INFORMATION FILED: 3–7–55, E. Dist. Mo., against **Leo Chelist, t/a Beltmar Pharmacy, St. Louis, Mo., and Frank Falsetti (a pharmacist).**

CHARGE: Between 8–4–54 and 8–16–54, *dextro-amphetamine sulfate tablets* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty—by each defendant.

DISPOSITION: 3–25–55. Chelist fined $500 and placed on probation for 1 year; Falsetti fined $250.

4817. (F. D. C. No. 37245. S. Nos. 53–845 L, 89–358 L, 89–714 L.)

INFORMATION FILED: 3–9–55, E. Dist. Mo., against **Fred A. Schultz, t/a F. A. Schultz Drug Co., University City, Mo.**

CHARGE: Between 6–9–54 and 6–18–54, *dextro-amphetamine sulfate tablets*, *Seconal Sodium capsules*, and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–11–55. $450 fine.

4818. (F. D. C. No. 37207. S. Nos. 53–836 L, 53–841 L, 63–072/3 L.)

INFORMATION FILED: 12–30–54, E. Dist. Ill., against **Fremont J. Hoehn, t/a Hoehn Drug Co., East St. Louis, Ill.**

CHARGE: Between 10–1–53 and 5–28–54, *dextro-amphetamine sulfate capsules*, *diethylstilbestrol tablets*, *penicillin G potassium tablets*, and *tablets containing a mixture of penicillin, sulfadiazine, sulfamerazine, and sulfamethazine* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–21–55. $400 fine, plus costs.

4819. (F. D. C. No. 37257. S. Nos. 8–052/54 L.)

INFORMATION FILED: 3–19–55, Dist. Nev., against **Blanche Lake, t/a Battle Creek Health Center, Reno, Nev.**

CHARGE: Between 3–25–54 and 3–30–54, *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–9–55. Imposition of sentence suspended and defendant placed on probation for 1 year.

4820. (F. D. C. No. 37217. S. Nos. 58–667/70 L, 65–781/2 L.)

INFORMATION FILED: 4–7–55, E. Dist. Mich., against **Day Drug Co. (a partnership), Detroit, Mich., and Edward A. Klar and Solomon Budney (partners and pharmacists).**

CHARGE: Between 3–12–54 and 4–1–54, *dextro-amphetamine sulfate tablets*, *methyltestosterone tablets*, and *methantheline bromide tablets* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1–23–56. Partnership fined $600 and Klar and Budney fined $600 jointly. Fine against Klar and Budney suspended for 1 year.

4821. (F. D. C. No. 35605. S. Nos. 65–765 L, 65–767 L.)

INFORMATION FILED: 4–7–55, E. Dist. Mich., against **Leonard Rosenberg (a partner in the partnership of A & L Drug Co.), Detroit, Mich., and Freddie Jones, Jr. (a pharmacist).**

CHARGE: Between 3–11–54 and 3–16–54, *dextro-amphetamine sulfate capsules* and *tablets containing a mixture of dextro-amphetamine sulfate and amobarbital* were each dispensed once without a prescription.

PLEA: Guilty—by Rosenberg to dispensing *dextro-amphetamine sulfate capsules* and by Jones to dispensing the other drug involved.

DISPOSITION: 12–15–55. Rosenberg fined $500 and Jones $100.

4822. (F. D. C. No. 35603. S. No. 58–660 L.)

INFORMATION FILED: 4–7–55, E. Dist. Mich., against **Henry Cohen, t/a Henry Drug Co., Detroit, Mich., and Samuel F. Katser (pharmacist).**

CHARGE: On 3–24–54, *Metandren Linguets* were dispensed once without a prescription.

PLEA: Guilty

DISPOSITION: 9–27–55. Each defendant fined $1,000 and sentenced to 1 year in prison. The prison sentences were suspended.

4823. **(3 informations.)** (F. D. C. No. 37239. S. Nos. 82–762 L, 82–764/6 L, 82–768 L.)

INFORMATIONS FILED: 5–11–55, W. Dist. Pa., against **Charles T. Poorman, t/a Strickler's Drug Store, Latrobe, Pa., and George E. Jamison and John A. Miller (pharmacists).**

CHARGE: Between 6–29–54 and 7–7–54, *Metandren Linguets*, *Gantrisin tablets*, and *Banthine tablets* were each dispensed once without a prescription, and *Tuinal capsules* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by Poorman to dispensing *Metandren Linguets*, by Jamison to dispensing *Gantrisin tablets* and one *Tuinal capsule* refill, and by Miller to dispensing *Banthine tablets* and one *Tuinal capsule* refill.

DISPOSITION: 6–27–55. Poorman fined $300, plus costs, and Jamison and Miller placed on probation for 6 months.

4824. (F. D. C. No. 37246. S. Nos. 59–705 L, 60–041 L, 60–054 L, 60–136 L, 60–138 L.)

INFORMATION FILED: 6–20–55, N. Dist. Ga., against **Boykin B. Dunaway and Lindsey B. Cobb (pharmacists for the Dunaway Drug Co.), Marietta, Ga.**

CHARGE: Between 10–15–53 and 1–8–54, *Metandren Linguets* (counts 1 and 3) were dispensed twice and *thyroid tablets* (count 2) were dispensed once without a prescription, and *pentobarbital sodium capsules* (counts 4 and 5) were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by Dunaway to counts 1 and 2 and by Cobb to counts 3, 4, and 5.

DISPOSITION: 6–24–55. Each defendant fined $200 and placed on probation for 2 years.

4825. (F. D. C. No. 35602. S. Nos. 58–674 L, 58–677 L.)

INFORMATION FILED: 4–7–55, E. Dist. Mich., against **John B. Sochocki, t/a Bernard's Drugs, Detroit, Mich., and Herbert L. Scott (a pharmacist).**

CHARGE: Between 3–24–54 and 4–2–54, *methyltestosterone tablets* and *sulfisoxazole tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Sochocki to dispensing *sulfisoxazole tablets* and by Scott to dispensing *methyltestosterone tablets.*

DISPOSITION: 11–22–55, Sochocki fined $500; 12–15–55, Scott fined $100.

4826. (F. D. C. No. 37852. S. No. 65–841 L.)

INFORMATION FILED: 6–1–55, E. Dist. Mich., against **Norman S. Shapiro (pharmacist for Spencer Pharmacy), Detroit, Mich.**

CHARGE: On 10–15–54, *methyltestosterone tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–26–56. $250 fine.

4827. (F. D. C. No. 37865. S. No. 8–642/5 M.)

INFORMATION FILED: 5–17–55, Dist. Nebr., against **Anton Hofmann, t/a Hofmann Pharmacy, Omaha, Nebr.**

CHARGE: Between 11–23–54 and 12–14–54 *methyltestosterone tablets* and *pentobarbital sodium capsules* were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 6–30–55. $40 fine, plus costs.

4828. (F. D. C. No. 35599. S. No. 58–653 L.)

INFORMATION FILED: 4–7–55, E. Dist. Mich., against **Jacob S. Fisher, t/a Fisher Drug Co., Detroit, Mich.**

CHARGE: On 3–26–54, *testosterone propionate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–7–55. $500 fine.

4829. (F. D. C. No. 37851. S. Nos. 75–405/6 L, 75–613/4 L.)

INFORMATION FILED: 4–25–55, E. Dist. N. C., against **Wilbur Royster Adams, t/a Carolina Beach Drug Co., Carolina Beach, N. C.**

CHARGE: Between 10–5–54 and 10–19–54, *Seconal Sodium capsules* and *Dexedrine Spansule capsules* were each dispensed twice upon requests for prescription refills without authorization by the prescribers.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court without a jury on 5–26–55, and was concluded on the same day, with a return of a verdict of guilty and the imposition of a fine of $100.

4830. (F. D. C. No. 37864. S. Nos. 75–391 L, 75–393 L, 75–603/4 L.)

INFORMATION FILED: 4–25–55, E. Dist. N. C., against **Joseph H. Clendenin, t/a Service Drug Store, Wilmington, N. C., and George D. Blakely and Alexander G. Millican (pharmacists).**

CHARGE: Between 9–29–54 and 10–19–54, *Seconal Sodium capsules* (counts 1 and 3) and *Dexedrine Sulfate tablets* (counts 2 and 4) were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court without a jury on 5–26–55, and was concluded on the same day, with a return of verdicts of guilty against Clendenin on each of 4 counts of the information, against Blakely on count 1, and against Millican on counts 2, 3, and 4, followed by the imposition of the following fines: Clendenin—$100, Blakely—$10, and Millican—$30.

4831. (F. D. C. No. 37857. S. Nos. 77–877 L, 77–881/3 L, 77–887/9 L.)

INFORMATION FILED: 4–21–55, S. Dist. W. Va., against **Williamson Medical Arts Pharmacy, Inc., Williamson, W. Va., and Patrick H. Conley (president).**

CHARGE: Between 10–14–54 and 10–28–54, *Seconal Sodium capsules* and *Gantrisin tablets* were each dispensed 3 times and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 6–2–55. Corporation fined $1,400. Individual sentenced to imprisonment for 9 months on each of 7 counts of information; sentence suspended and placed on probation for 5 years.

4832. (F. D. C. No. 37220. S. Nos. 38–544 L, 72–114 L, 72–121/2 L.)

INFORMATION FILED: 7–14–55, E. Dist. N. Y., against **Nassau Chemists (a partnership), Baldwin, N. Y., and Saul Witheiler and Harry Lichtiger (partners).**

CHARGE: Between 5–11–54 and 6–3–54, *Seconal Sodium capsules* were dispensed twice and *Gantrisin tablets* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty—by partnership to all charges reported herein, by Witheiler to dispensing *Gantrisin tablets* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium*, and by Lichtiger to dispensing *Seconal Sodium capsules.*

DISPOSITION: 8–11–55. Partnership fined $100 and each individual fined $700.

4833. (F. D. C. No. 37249. S. Nos. 60–267/8 L, 60–442 L, 60–446 L, 60–540 L, 60–542 L.)

INFORMATION FILED: 5–11–55, S. Dist. Fla., against **Abraham A. Golden (manager of the store of Whelan Drug Co., Inc.), 200 Lincoln Road, Miami Beach, Fla., and Albert P. Winston and Harold K. Brown (pharmacists).**

CHARGE: Between 4–6–54 and 4–12–54, *Gantrisin tablets* (count 5) and *terramycin hydrochloride capsules* (count 6) were each dispensed once without a prescription, and *pentobarbital sodium capsules* were dispensed 3 times (counts 1, 2, and 4) and *Dexedrine Sulfate tablets* (count 3) were dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere—by Golden to all 6 counts of information, by Winston to counts 1, 2, and 3, and by Brown to count 4.

DISPOSITION: 5–23–55. Fine of $450 against Golden, $225 against Winston, and $75 against Brown.

4834. (F. D. C. No. 37172. S. Nos. 84–811/3 L, 85–069/70 L.)

INFORMATION FILED: 12–20–54, E. Dist. Pa., against **Harry Z. Kroser, t/a Kroser's Pharmacy, Philadelphia, Pa., and Florence Kroser (a clerk at the pharmacy).**

CHARGE: Between 3–16–54 and 4–2–54, *Gantrisin tablets* (counts 2 and 4) and *Gynergen tablets* (counts 3 and 5) were each dispensed twice and *thyroid tablets* (count 1) were dispensed once without a prescription.

PLEA: Guilty—by Harry Z. Kroser to all counts of information; not guilty—by Florence Kroser to counts 1, 2, and 4, which plea was changed to nolo contendere.

DISPOSITION: 5–11–55. Harry Kroser fined $550, given a 1-year suspended jail sentence, and placed on probation for 3 years.

On 6–8–55, the case against Florence Kroser came on for trial upon her plea of not guilty. In the course of the trial, Florence Kroser offered to change her plea to nolo contendere. The court accepted this plea and fined her $50 on count 1 and suspended the imposition of sentence against her on counts 2 and 4.

4835. (F. D. C. No. 37211. S. Nos. 75–725 L, 75–729 L.)

INFORMATION FILED: 8–8–55, Dist. Columbia, against **Walter Rosenberg and Morris Rosenberg (pharmacists for the Woodley Drug Store), Washington, D. C.**

CHARGE: Between 7–6–54 and 7–21–54, *Gantrisin tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 8–8–55. Each defendant fined $300.

4836. (F. D. C. No. 36585. S. Nos. 85–111 L, 85–117 L.)

INFORMATION FILED: 8–2–54, E. Dist. Pa., against **George H. Gibson, t/a Gibson's Pharmacy, Philadelphia, Pa.**

CHARGE: Between 10–12–53 and 10–16–53, *apiol capsules* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 9–30–55. The court found the defendant guilty. Thereafter, the defendant filed a motion for a new trial, which the court dismissed on 11–14–55, handing down the following opinion:

KRAFT, *District Judge:* "The defendant was tried without a jury and adjudged guilty upon two counts of an indictment which charged him with having, on October 12 and October 16, 1953, dispensed certain drugs without a prescription in violation of the Food and Drugs Act. This Act prohibits, inter alia, the

misbranding of any drug held for sale after shipment in interstate commerce.[1] Misbranding is defined to include the dispensing of the drug contrary to the provisions of the Act.[2] The drug involved in this case was one which the Act required to be dispensed upon a physician's written prescription.

"Defendant bases his motion for a new trial on three grounds. The first, that Exhibit 5 was improperly admitted, is wholly devoid of merit. The testimony of Mrs. Allen and Mr. Schneider adequately identified this exhibit as the purchase made from the defendant by Mrs. Allen on October 16, 1953.

"The next contention is that in ascertaining the meaning of 'misbranded' no consideration may be given to the statutory definition. The two sections must be read together to ascertain the meaning of 'misbranded' as used in the Act. It is provided that the prohibited act of dispensing such drug without prescription 'shall be deemed to be an act which results in the drug being misbranded while held for sale.'[3]

"Defendant's final contention is that the defense of entrapment should have been sustained with resultant acquittal. The trial judge very carefully considered the evidence in light of the principles applicable to the defense of entrapment as announced in Sorrells v. United States, 287 U. S. 435; United States v. Sawyer, 210 F. 2d 169 and United States v. Moses, 220 F. 2d 166. The trial judge concluded that the criminal design here was not created by the conduct of the public officers or their lay assistant, Mrs. Allen; but that, on the contrary, the defendant, already disposed to make such a prohibited sale, readily seized the opportunity which was afforded by the officers through Mrs. Allen.

"The evidence to support the conclusion of the trial judge was ample. Mrs. Allen was employed by the Food and Drug Administration as a laboratory helper. She occasionally assisted the inspectors in their investigations. On October 5, 1953, she first visited defendant's pharmacy and told him she was 'a little late.' She asked the defendant if he would give her something to help. Defendant asked if she had ever taken anything before. She described a tablet by shape and color and defendant told her he had none on hand but would get it for her on Friday. Defendant then took out a book and wrote the world 'ergot.' Defendant gave her some pills to take meanwhile.

"On October 12 Mrs. Allen returned to the defendant's pharmacy. As she approached the counter defendant asked: 'Didn't it he'p?' He then sold her, without the required prescription, the package of Savatan. He first stated the price, as $2.00 and then increased it to $5.00. When Mrs. Allen asked if there were any directions in the package defendant told her that there were not because they were supposed to be sold with a prescription. He then instructed her to take two every three hours and two at bed time followed by a hot toddy.

"Mrs. Allen again visited the pharmacy on October 16, 1953. Defendant inquired how she felt and asked: 'Did it work?' She informed defendant that it had worked a little but not as well as she had hoped. Defendant then said to Mrs. Allen 'Maybe another dose would do the trick.' She said she had been about to suggest that and defendant sold her, without prescription, another package of the drug for $5.00. Defendant requested no prescription at the time of either sale.

"Defendant testified that he sold Mrs. Allen quinine and cascara on her first two visits but admitted the sale of the drug, without prescription, on her third visit. However, a letter prepared and signed by defendant, dated January 15, 1954, admitted the two sales of the drug to Mrs. Allen, without prescription, on the dates in question. Defendant further testified that he had made sales of the same drug six or seven years before and that no prescription was then required and that he was unaware that a prescription was required at the time of the sales to Mrs. Allen. This testimony is in direct conflict with the testimony of Mrs. Allen, which the trial judge credited, to the effect that defendant told her that there were no directions in the package because the contents were supposed to be sold with a prescription."

On 11–21–55, the defendant was fined $200 and placed on probation for 2 years.

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[1] 21 U. S. C. § 333.
[2] *Id.* § 353(b)(1).
[3] *Ibid.*

4837. (F. D. C. No. 37250. S. Nos. 66–968/9 L, 66–971 L.)

INFORMATION FILED: On or about 3–22–55, E. Dist. Pa., against **Adams Drug Store, a partnership, Reading, Pa., and Oliver F. Adams (a partner).**

CHARGE: Between 6–9–53 and 6–18–53, *capsules containing ergot* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9–9–55. Partnership fined $150 and individual $300.

4838. (F. D. C. No. 37212. S. Nos. 84–823 L, 84–827/8 L, 84–917 L.)

INFORMATION FILED: 2–25–55, E. Dist. Pa., against **Harry G. Bobman (a pharmacist for Shanker's Pharmacy), Philadelphia, Pa.**

CHARGE: Between 5–18–54 and 6–10–54, *pills containing ergotin, aloe, and oil tansy*, and *thyroid tablets* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6–29–55. $100 fine.

4839. (F. D. C. No. 35161. S. Nos. 9–693 L, 10–072 L, 10–074 L, 10–076/7 L, 54–176 L, 54–182/3 L, 54–190 L, 54–194/5 L.)

INFORMATION FILED: 9–9–53, N. Dist. Ind., against **Robert M. Stitzer, t/a Morningside Pharmacy, South Bend, Ind., and Constance L. Froning, Henry A. Meers, and James O. Worster (pharmacists).**

CHARGE: Between 9–9–52 and 12–3–52, *pentobarbital sodium capsules* were dispensed seven times (counts 1 to 7, incl.) and *dextro-amphetamine sulfate tablets* were dispensed four times (counts 8 to 11, incl.) upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by Stitzer to each of 11 counts of information, by Froning to counts 1, 2, 4, 5, and 8, by Meers to counts 7 and 11, and by Worster to counts 9 and 10.

DISPOSITION: 4–28–54. Stitzer—$300 fine, plus costs; each of remaining defendants—$100 fine.

4840. (F. D. C. No. 37843. S. Nos. 15–090/1 M, 15–282 M.)

INFORMATION FILED: 4–8–55, N. Dist. Calif., against **Walter Powell, Jr., t/a Powell Jr. Pharmacy, San Francisco, Calif.**

CHARGE: On 1–28–55, *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–19–55. Fine of $750 and probation for 2 years.

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PRODUCTS

[1] (4813, 4829, 4830, 4834) Prosecution contested.
[2] (4810, 4836) Prosecution contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4813, 4829, 4830, 4834) Prosecution contested.
[2] (4810, 4836) Prosecution contested. Contains opinion of the court.

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4841–4880

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 18, 1956.*

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407477—56——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4841. (F. D. C. No. 37195. S. Nos. 60–264 L, 60–270 L, 60–425 L.)

INDICTMENT RETURNED: 4–14–55, S. Dist. Fla., against **Robert G. Wheeler, t/a Wheeler's Rexall Pharmacy, Dania, Fla., and Richard J. Bonin (pharmacist).**

CHARGE: Between 3–9–54 and 4–13–54, *secobarbital sodium capsules* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere—by Bonin to dispensing *secobarbital sodium capsules* once and *dextro-amphetamine sulfate tablets* once; guilty—by Wheeler to dispensing *secobarbital sodium capsules* once.

DISPOSITION: 1–27–56. Bonin fined $100; Wheeler fined $500 and placed on probation for 1 year.

4842. (F. D. C. No. 37188. S. Nos. 60–532/3 L.)

INFORMATION FILED: 3–29–55, S. Dist. Florida, against **George Dewey McCallum, Sr., t/a Springfield Drug Store, Jacksonville, Fla., and Paul E. Haile (a pharmacist).**

CHARGE: On 2–10–54, *secobarbital sodium capsules* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by McCallum to dispensing both of the unauthorized refills and by Haile to dispensing one of the refills.

DISPOSITION: 6–3–55. McCallum—$250 fine; Haile—$100 fine.

4843. (F. D. C. No. 38127. S. Nos. 2–865/6 M, 2–870 M, 2–874 M, 3–446 M, 3–450 M, 3–648 M.)

INFORMATION FILED: 8–10–55, Dist. Mass., against **Nelson's Pharmacy, Inc., Lynn, Mass., and Hyman Levy and Francis Murphy (pharmacists).**

CHARGE: Between 3–15–55 and 3–29–55, *secobarbital sodium capsules* were dispensed twice and *Butazolidin tablets* and *Pentids tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber; and *Premarin tablets*, *pentobarbital sodium capsules*, and *AM Plus capsules* were each dispensed once without a prescription.

PLEA: Guilty—by corporation and Levy to all counts of information and by Murphy to dispensing *secobarbital sodium capsules*, *Butazolidin tablets*, and *AM Plus capsules*.

DISPOSITION: 10–10–55. Corporation fined $500 and each individual $150.

4844. (F. D. C. No. 36594. S. Nos. 14–731/2 L, 14–748 L.)

INFORMATION FILED: 7–16–54, Dist. Colo., against **Homer N. Archambault, Westcreek, Colo.**

CHARGE: Between 7–31–53 and 11–18–53, *pentobarbital sodium capsules* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: On 10–8–54, the case came on for trial before the court and jury; and, on 10–11–54, the jury returned a verdict of guilty. The defendant filed motions for a new trial and in arrest of judgment, which the court denied on 10–27–54.

On 11–17–54, the court sentenced the defendant to 10 months in prison, fined him $2,000, and placed him on probation for 3 years. The defendant took an

appeal to the United States Court of Appeals for the Tenth Circuit. On 5–26–55, the case was argued before the appellate court; and, on 7–16–55, the court handed down the following opinion, affirming the judgment of the district court:

PICKETT, *Circuit Judge:* "The defendant was charged in a three-count information with dispensing misbranded habit-forming drugs in unlabeled containers without a prescription contrary to the provisions of 21 U. S. C. A. Secs. 331, 333, and 353. The charge grew out of three different sales of sodium pentobarbital capsules which the defendant made to George E. McDonald, an inspector for the United States Food and Drug Administration. The case went to the jury on the evidence of the prosecution and a verdict of guilty was returned on all three counts. The defendant was sentenced to imprisonment for ten months and was fined Five Hundred Dollars on counts one and two, the imprisonment sentences to run concurrently. On count three, the defendant was fined One Thousand Dollars, but the sentence of imprisonment was suspended and probation was imposed for three years commencing at the expiration of the sentence imposed on counts one and two. This appeal is from that judgment and sentence.

"The defendant maintained a place of business in Westcreek, Colorado, where he treated patients and dispensed some drugs. He held himself out as a doctor of medicine, but he had never been licensed to practice in Colorado although he had applied for a license. McDonald, dressed as an outdoorsman, first called on the defendant at his office on July 31, 1953. Upon inquiry, the defendant identified himself as 'Dr. Archambault.' McDonald stated to him that he was having difficulty sleeping and wanted to buy some sleeping pills. The defendant questioned him about his condition and sold him a number of sodium pentobarbital capsules, known as Nembutal, which is a trade name for sodium pentobarbital manufactured by Abbott Laboratories in North Chicago, Illinois. Subsequent purchases of the same drug were made by McDonald on August 21 and November 18, 1953. After each purchase, the defendant placed the capsules in a plain unlabeled envelope and delivered them to McDonald.

"The defendant first contends that the court was without jurisdiction because the prosecution should have been under an indictment and not an information. The basis of this contention is that the cumulative penalty in the three counts is for imprisonment for more than one year, and that the defendant had not waived indictment as required by the Federal Rules of Criminal Procedure. Fed. Rules Cr. Proc. rule 7 (a), 18 U. S. C. A. There is no merit to this contention. Each of the counts charged a separate offense constituting a misdemeanor and punishable by imprisonment of not more than one year. 21 U. S. C. A. Sec. 333 (a). Such offenses may be prosecuted by information. Fed. Rules Cr. Proc. rule 7 (a), supra; Duke v. United States, 301 U. S. 492; United States v. Kordel, 7 Cir., 164 F. 2d. 913, affirmed 335 U. S. 345; Kempe v. United States, 8 Cir., 151 F. 2d. 680; American Tobacco Co. v. United States, 6 Cir., 147 F. 2d. 93, affirmed 328 U. S. 781; Taylor v. United States, 9 Cir., 142 F. 2d. 808, cert. den. 323 U. S. 723; Grader v. United States, 8 Cir., 21 F. 2d. 513. The charges in the different counts were of the same character and were properly joined. Fed. Rules Cr. Proc. rule 8 (a), 18 U. S. C. A.; Peckham v. United States, App. D. C., 210 F. 2d 693; Robinson v United States, App. D. C., 210 F. 2d. 29; Finnegan v. United States, 8 Cir., 204 F. 2d. 105, cert. den. 346 U. S. 821; Smith v. United States, App. D. C., 180 F. 2d. 775; Edwards v. Squier, 9 Cir., 178 F. 2d. 758.

"Section 331 (k) of Title 21 prohibits the doing of any act with respect to drugs if such act is done while the drug 'is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.' 21 U. S. C. A. Sec. 352[1] makes

[1] Section 352 (d) reads:
"If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement 'Warning—May be habit forming.'"

provision for the proper labeling of drugs, and provides that if a drug contains any quantity of narcotic or barbituric acid or any chemical derivative thereof which has been found and designated by the Secretary[2] as habit forming, it shall be so labeled, and that if it is not so labeled, it is deemed to be misbranded. Under the provisions of 21 U. S. C. A. Sec. 353, such drugs may be dispensed only upon a written prescription of a practitioner licensed by law to administer such drug. The regulation adopted by the Secretary designated pentobarbital, a derivative of barbituric acid, as habit forming (21 C. F. R. Sec. 145.1). Section 352 (d) of Title 21 declares that drugs shall be deemed to be misbranded if they are designated by the Secretary by regulation to be habit forming, unless they bear the statutory label. This regulation having been promulgated by the Secretary in conformity with the statute has the force and effect of law to the same extent as though written into the statute. Atchison, Topeka & Santa Fe Railway Co. v. Scarlett, 300 U. S. 471; Maryland Casualty Co. v. United States, 251 U. S. 342; Interstate Motor Lines, Inc. v. Great Western Ry. Co., 10 Cir., 161 F. 2d 968; Regents of New Mexico College of Agriculture & Mechanic Arts v. Albuquerque Broadcasting Co., 10 Cir., 158 F. 2d 900; United States v. Stanolind Crude Oil Purchasing Co., 10 Cir., 113 F. 2d. 194. When a drug is so designated by regulation it must be considered 'habit forming' as a matter of law and no further proof is necessary.

"The defendant contends that there is no evidence that the drugs purchased by McDonald had been transported in interstate commerce. The capsules were identified as having been manufactured and sold in Illinois by Abbott Laboratories. They were later held for sale and sold by the defendant without a prescription and without the statutory label after they had arrived in Colorado. Their method of transportation is unknown. We think, however, that this makes no difference as the inference is inescapable that they were transported from Illinois to Colorado. This constitutes interstate commerce even though the defendant may have acquired the capsules in Illinois and transported them himself to Colorado. National Labor Relations Board v. Fainblatt, 306 U. S. 601; Dahnke-Walker Milling Co. v. Bondurant, 257 U. S. 282; United States v. Simpson, 252 U. S. 465; United States v. Hill, 248 U. S. 420; United States v. Sanders, 10 Cir., 196 F. 2d 895, cert. den. 344 U. S. 829; Bell v. Porter, 7 Cir., 159 F. 2d 117, cert. den. 330 U. S. 813; Barnes v. United States, 9 Cir., 142 F. 2d 648.[3]

"It is immaterial when or how the defendant may have obtained title and possession of the drugs after the interstate shipment. The purpose of the statute is to protect the ultimate consumer and it 'prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment.' United States v. Sullivan, 332 U. S. 689; Strey v. Devine's, Inc., 7 Cir., 217 F. 2d. 187, 190. In United States v. 4 Devices, Labeled in Part 'Color-therm,' 10 Cir., 176 F. 2d. 652, we said:

> The purpose of the Act is to safeguard the consumer by applying its requirements to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer, and the Act embraces misbranding while held for sale after shipment in interstate commerce. (footnote omitted.)

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[2] Secretary of the Department of Health, Education and Welfare.

[3] In Bell v. Porter, supra, the court said:

"The Constitution confers upon Congress the power to regulate commerce among the several States. U. S. Const. Art. 1, Sec. 8, cl. 3. This power to regulate commerce is not confined to commercial or business transactions. From an early date such commerce has been held to include the transportation of persons and property no less than the purchase, sale, and exchange of commodities, United States v. Hill, 248 U. S. 420, 423, 39 S. Ct. 143, 63 L. Ed. 337, and goods may move in commerce though they never enter the field of commercial competition. For example, the movement of people across State lines and the unrestricted ranging of cattle across the boundary between two States is commerce. The interstate transportation of whiskey for personal consumption, of a woman from one State to another for an immoral purpose without any element of commerce, of a kidnapped person or a stolen automobile—all constitute interstate commerce in the constitutional sense. These cases, we think, make it clear that interstate commerce is not limited to interstate trade." (Footnote omitted.)

"Finally, it is urged that the trial court should have sustained the defendant's motion for a directed verdict because the proof showed that the defendant had been entrapped into the commission of the offense by McDonald. There is no evidence that the inspector did anything more than call at the defendant's office and offer an opportunity for the defendant to make the sale of the drugs. This, he had the legal right to do. Sorrells v. United States, 287 U. S. 435; Ryles v. United States, 10 Cir., 183 F. 2d. 944, cert. den. 340 U. S. 877. The trial court, however, assumed that an issue of entrapment was presented and submitted that issue to the jury with the proper instruction. AFFIRMED."

4845. (F. D. C. No. 38510. S. Nos. 16-181 M, 16-191/4 M.)

INFORMATION FILED: 11-3-55, Dist. Mont., against **Ronan Drug Co. (a partnership), Ronan, Mont., and Norman D. Coster (a partner).**

CHARGE: Between 1-19-55 and 3-24-55, *pentobarbital sodium capsules*, *Seconal Sodium capsules*, and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were each dispensed once without a prescription, and *Seconal Sodium capsules* and *pentobarbital sodium capsules* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 11-28-55. Partnership—$250 fine; individual—prison sentence of 3 months suspended and probation for 2 years.

4846. (F. D. C. No. 37874. S. Nos. 60-591 L, 60-595 L, 60-670 L, 60-721 L, 60-872 L, 60-889 L.)

INFORMATION FILED: 9-7-55, W. Dist. S. C., against **Julius E. Robinson, t/a Robinson Drug Store, Greenville, S. C., and Robert R. Ridgeway (a pharmacist), and Charles E. Edwards (an employee).**

CHARGE: Between 7-31-54 and 9-28-54, *pentobarbital sodium capsules* (counts 1, 2, and 3) and *dextro-amphetamine sulfate tablets* (counts 4, 5, and 6) were each dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by Julius E. Robinson to each of 6 counts of information; by Charles E. Edwards to counts 1, 2, and 3; and by Robert R. Ridgeway to count 6.

DISPOSITION: 10-24-55. Robinson fined $100 and each of other individuals $25.

4847. (F. D. C. No. 37861. S. Nos. 13-905/6 M, 13-913/4 M, 14-305/6 M.)

INFORMATION FILED: 5-10-55, W. Dist. Tenn., against **Edward M. Mehr, t/a Mehr Drug Store, Bells, Tenn., and Otto Williams (a pharmacist).**

CHARGE: Between 1-7-55 and 1-11-55, *Pentids tablets*, *Dexedrine Spansule capsules*, *Benzedrine Sulfate tablets*, *sulfisoxazole tablets*, *thyroid tablets*, and *penicillin tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Mehr to all counts of information and by Williams to counts involving dispensing of *thyroid tablets* and *penicillin tablets*.

DISPOSITION: 6-20-55. Mehr fined $1,500 and Williams $500.

4848. (F. D. C. No. 38156. S. Nos. 4-772 M, 4-776 M, 5-125 M, 5-738 M, 5-740 M.)

INFORMATION FILED: 10-5-55, N. Dist. Ill., against **Paul H. Pohlman, t/a Pohlman's Pharmacy, Barrington, Ill., and William F. Schroeder (apprentice pharmacist).**

CHARGE: Between 12–14–54 and 2–5–55, *Pentids tablets* were dispensed three times, *Gantrisin tablets* were dispensed once, and *Pondets troches* were dispensed once without a prescription.

PLEA: Nolo contendere—by Pohlman to all counts and by Schroeder to dispensing *Pentids tablets* twice and *Pondets troches* once.

DISPOSITION: 11–7–55. Pohlman fined $250, plus costs, and Schroeder $150.

4849. (F. D. C. No. 38116. S. Nos. 3–422 M, 3–438/9 M, 3–607/8 M.)

INFORMATION FILED: 7–20–55, Dist. N. H., against **Kenneth K. Abetz (pharmacist for Claremont Pharmacy), Claremont, N. H.**

CHARGE: Between 2–10–55 and 3–8–55, *Pentids tablets* were dispensed once upon a request for a prescription refill without authorization by the prescriber, and *secobarbital sodium capsules* were dispensed twice and *penicillin G troches* and *sulfadiazine tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–14–55. $200 fine.

4850. (F. D. C. No. 38111. S. No. 11–381 M.)

INFORMATION FILED: 7–27–55, S. Dist. Tex., against **Samuel H. Stone (manager of Store No. 1 of Ranger Drugs, Inc.), Houston, Tex.**

CHARGE: On 12–4–54, *Penicillin tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–23–55. Defendant sentenced to 90 days in jail; sentence suspended and defendant placed on probation for 3 years.

4851. (F. D. C. No. 35621. S. Nos. 48–148 L, 67–322 L, 67–731 L, 67–737 L, 67–739 L.)

INFORMATION FILED: 5–18–55, S. Dist Ala., against **Walter G. English, t/a English Drug Store, Mobile, Ala., and Jack G. Moore (a pharmacist).**

CHARGE: Between 3–26–54 and 4–8–54, *penicillin tablets* were dispensed twice without a prescription and *dextro-amphetamine sulfate tablets* were dispensed three times upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6–2–55. English—$300 fine; $200 remitted by court. Moore—$100 fine; all remitted by court.

4852. (F. D. C. No. 38128. S. Nos. 11–001/3 M.)

INFORMATION FILED: 8–22–55, N. Dist. Miss., against **Edward A. Furr, t/a Furr Drug Co., Tupelo, Miss.**

CHARGE: Between 1–24–55 and 1–25–55, *penicillin tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9–16–55. $50 fine.

4853. (F. D. C. No. 38146. S. Nos. 9-255/7 M.)

INFORMATION FILED: 11-4-55, S. Dist. Calif., against **Eugene W. Gunther, t/a Gunther Drug Co., Beverly Hills, Calif., and Gard V. Edwards (pharmacist).**

CHARGE: Between 2-4-55 and 3-4-55, *Dexedrine Sulfate tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by Gunther to counts 1 and 3 and by Edwards to counts 1 and 2.

DISPOSITION: 12-19-55. Gunther fined $200 and Edwards $50.

4854. (F. D. C. No. 38148. S. Nos. 6-010 M, 6-530 M, 6-546 M.)

INFORMATION FILED: 11-8-55, E. Dist. Tenn., against **George D. Carnes and Robert A. Webb (pharmacists for Vineyard Drug Store), Knoxville, Tenn.**

CHARGE: Between 12-8-54 and 2-2-55, *Dexedrine Sulfate tablets, capsules containing Amytal,* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Webb to dispensing *Dexedrine Sulfate tablets* and *thyroid tablets* and by Carnes to dispensing *capsules containing Amytal.*

DISPOSITION: 1-17-56. Each defendant fined $50 and placed on probation for 1 year.

4855. (F. D. C. No. 38124. S. Nos. 60-298 L, 60-466 L, 60-502 L, 60-685 L, 60-771 L, 60-784/5 L.)

INFORMATION FILED: 8-17-55, S. Dist. Fla., against **Samuel E. Spaulding, t/a Wild Cat Pharmacy, Miami, Fla.**

CHARGE: Between 5-18-54 and 9-2-54, *Dexedrine Sulfate tablets* were dispensed 3 times and *Gantrisin tablets* and *cortisone acetate tablets* were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 9-23-55. $100 fine and probation for 2 years.

4856. (F. D. C. No. 37885. S. Nos. 60-575 L, 60-604 L, 60-660 L, 60-876 L, 60-879 L, 60-880 L.)

INFORMATION FILED: 9-7-55, W. Dist. S. C., against **Peoples Pharmacy (a corporation), Anderson, S. C., and John Ellis Evans (president).**

CHARGE: Between 7-1-54 and 9-16-54, *Dexedrine Sulfate tablets* were dispensed twice and *pentobarbital sodium capsules* were dispensed once without a prescription, and *Seconal Sodium capsules* were dispensed twice and *pentobarbital sodium capsules* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 10-24-55. Corporation—$1.00 fine and individual $250 fine.

4857. (F. D. C. No. 37875. S. Nos. 60-592 L, 60-597 L, 60-668 L, 60-722 L, 60-873 L, 60-881 L, 60-887 L.)

INFORMATION FILED: 9-7-55, W. Dist. S. C., against **Joseph E. Shaw, Jr., t/a Shaw's Pharmacy No. 1, Greenville, S. C., Sidney J. Jarrett (a pharmacist), and Edward J. McCall and Fred H. Roberts (employees).**

CHARGE: Between 7–31–54 and 9–27–54, *dextro-amphetamine sulfate tablets* were dispensed 3 times (counts 1, 2, and 3) and *Nembutal Sodium capsules* were dispensed 4 times (counts 4, 5, 6, and 7) upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by Joseph E. Shaw, Jr., to each of 7 counts of information; by Fred H. Roberts to counts 1 and 7; by Edward J. McCall to counts 3 and 6; and by Sidney J. Jarrett to count 5.

DISPOSITION: 10–24–55. Shaw fined $100 and each of other individuals $25.

4858. (F. D. C. No. 38121. S. Nos. 5–844 M, 6–363 M, 6–548 M, 6–576 M.)

INFORMATION FILED: 8–2–55, E. Dist. Tenn., against **Ernest E. Moon, Frederic I. Scott, George M. Sharp, and H. James J. Mugford.** Moon and Sharp were employees of, and Scott and Mugford were pharmacists for, W. C. Sharp Drug Store No. 3, Knoxville, Tenn.

CHARGE: Between 12–8–54 and 2–2–55, *dextro-amphetamine sulfate tablets* and *Metandren Linguets* were each dispensed twice without a prescription.

PLEA: Guilty—by Moon and Mugford to dispensing *dextro-amphetamine sulfate tablets* and by Sharp to dispensing *Metandren Linguets;* nolo contendere—by Scott to dispensing *Metandren Linguets.*

DISPOSITION: 9–1–55. Sharp fined $50; 1–17–56, Moon fined $200 and placed on probation for 1 year, Scott fined $50, and Mugford fined $500 and placed on probation for 1 year.

4859. (F. D. C. No. 38112. S. Nos. 7–703/4 M, 7–706 M, 7–710/1 M, 7–713 M.)

INFORMATION FILED: 8–2–55, N. Dist. Tex., against **George C. M. Koneval (a partner in Indian Head Drug Co.), Amarillo, Tex.**

CHARGE: Between 3–11–55 and 3–15–55, *Diphetamine tablets, pentobarbital sodium capsules,* and *secobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12–13–55. Defendant sentenced to prison for 5 months.

4860. (F. D. C. No. 38531. S. Nos. 16–930/32 M.)

INFORMATION FILED: 10–25–55, W. Dist. Va., against **Paul Briggs (an employee of Jimmy's Truck Stop), Cana, Va.**

CHARGE: Between 8–11–55 and 8–18–55, *dextro-amphetamine sulfate tablets* were dispensed twice and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–9–56. Defendant sentenced to prison for 1 year.

4861. (F. D. C. No. 38528. S. Nos. 833 M, 1–688 M, 1–691 M, 1–693 M, 1–695/6 M.)

INFORMATION FILED: 10–24–55, E. Dist. S. C., against **Thomas L. Rhodes, t/a Rhodes Truck Stop, U. S. Highway 301, Summerton, S. C., and George Goettee, Mozzell Gedding, and Hicky Welch (employees).**

CHARGE: Between 1–15–55 and 5–12–55, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Nolo contendere—by Rhodes to counts 1 and 5; by Goettee to counts 2 and 3; by Gedding to count 4; and by Welch to count 6.

DISPOSITION: 1-16-56. Rhodes fined $300 and each of the other defendants fined $50.

4862. (F. D. C. No. 38530. S. Nos. 16-923/8 M.)

INFORMATION FILED: 10-25-55, W. Dist. Va., against **C. Alton Ferrell, t/a Ferrell's Gulf Service, U. S. Highways 360 and 15, Wylliesburg, Va., and Raleigh Osborne (an employee).**

CHARGE: Between 8-9-55 and 8-19-55, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty—by Ferrell to each of 6 counts of information and by Osborne to count 5.

DISPOSITION: 2-13-56. Ferrell—$250 fine, jail sentence for 1 year suspended, and probation for 3 years; Osborne—jail sentence for 6 months suspended and probation for 1 year.

4863. (F. D. C. No. 38173. S. No. 1-705 M.)

INFORMATION FILED: 10-25-55, M. Dist. N. C., against **William Donald Horton (a partner in, and pharmacist for, Horton Drug Co.), North Wilkesboro, N. C., and Robert F. Shoemaker (an employee).**

CHARGE: On 5-16-55, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-13-55. Horton—$750 fine; Shoemaker—$500 fine. Both defendants placed on probation for 12 months.

4864. (F. D. C. No. 38171. S. Nos. 1-703/4 M, 1-751/2 M.)

INFORMATION FILED: 10-25-55, W. Dist. N. C., against **Jake C. Bagwell, Charlotte, N. C.**

CHARGE: Between 5-17-55 and 6-5-55, *amphetamine sulfate tablets* were dispensed twice and *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-3-56. $500 fine, sentence to imprisonment for 1 year suspended, and defendant placed on probation for 2 years.

4865. (F. D. C. No. 38172. S. Nos. 1-699/700 M, 1-721/2 M.)

INFORMATION FILED: 10-25-55, W. Dist. N. C., against **William Lee Francis (an employee of Lee's Truck Stop), Charlotte, N. C.**

CHARGE: Between 5-15-55 and 5-24-55, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4-3-56. $300 fine, sentence to imprisonment for 1 year suspended, and defendant placed on probation for 2 years.

4866. (F. D. C. No. 38174. S. Nos. 1-726 M, 27-743 M.)

INFORMATION FILED: 10-25-55, M. Dist. N. C., against **John Palmer Horton, Jr. (vice president of, and pharmacist for, Peoples Drug Store), Wilkesboro, N. C.**

CHARGE: Between 5-25-55 and 6-15-55, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12–13–55. Horton fined $1,000 and placed on probation for 12 months.

4867. (F. D. C. No. 38158. S. Nos. 1–725 M, 1–727 M, 1–749/50 M, 27–744 M.)

INFORMATION FILED: 10–25–55, M. Dist. N. C., against **Frank S. Barr, t/a Frank's Truck Stop, U. S. Highway 52 North, Rural Hall, N. C., and Beulah Mae Barr (an employee).**

CHARGE: Between 5–25–55 and 6–15–55, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty—by Frank S. Barr to all counts of information and by Beulah Mae Barr to count 1.

DISPOSITION: 12–13–55. Frank S. Barr—$500 fine; Beulah Mae Barr—$100 fine. Both defendants placed on probation for 12 months.

4868. (F. D. C. No. 38159. S. Nos. 1–747/8 M, 1–755/6 M.)

INFORMATION FILED: 10–25–55, W. Dist. S. C., against **Arthur L. Owen (operator of Bunny's Cafe Truck Stop, U. S. Highway 378, east of McCormick, S. C.**

CHARGE: Betweeen 6–3–55 and 6–6–55, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 12–5–55. The defendant was fined $4,000 and sentenced to prison for 4 years. The fine and sentence were suspended, and the defendant was placed on probation for 5 years and fined $300.

4869. (F. D. C. No. 38168. S. Nos. 1–728/30 M, 1–753/4 M, 1–757 M.)

INFORMATION FILED: 10–25–55, W. Dist. S. C., against **W. Russell Dover (manager of Rock Cafe & Service Station), Anderson, S. C., and Helen Pisano and Lois Hames (employees).**

CHARGE: Between 5–26–55 and 6–6–55, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty—by Dover to counts 1, 2, and 3 of the information; by Pisano to counts 4 and 5; and by Hames to count 6.

DISPOSITION: 2–20–56. Dover sentenced to pay $1,000 fine or serve 1 year in prison. The fine and sentence were to be suspended, provided that Dover pay a $300 fine and be placed on probation for 3 years. Imposition of sentence against Pisano and Hames was suspended, and each was placed on probation for 2 years.

4870. (F. D. C. No. 38160. S. Nos. 1–690 M, 1–692 M, 1–698 M, 1–719 M.)

INFORMATION FILED: 10–25–55, E. Dist. S. C., against **J. Norman Williams (an employee of Dixie Truck Terminal, Inc.), Bishopville, S. C.**

CHARGE: Between 5–10–55 and 5–23–55, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2–7–56. Defendant fined $100 and sentenced to 12 months in prison. The fine and sentence were suspended, and the defendant was placed on probation for 3 years.

4871. (F. D. C. No. 38169. S. Nos. 1–701/2 M, 1–723/4 M.)

INFORMATION FILED: 10–25–55, M. Dist. N. C., against **Thomas Paul Traywick, t/a Trucker's Center, U. S. Highway 29, north of Concord, N. C., and Ray Payne (an employee).**

CHARGE: Between 5–15–55 and 5–24–55, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty—by Traywick to 4 counts of information and by Payne to 2 counts.

DISPOSITION: 12–13–55. Traywick fined $500; Payne fined $100. Each defendant placed on probation for 12 months.

4872. (F. D. C. No. 38524. S. Nos. 21–424/7 M.)

INFORMATION FILED: 2–17–56, W. Dist. Mo., against **James Bradley, Jr. (a partner in the partnership of Bradley's Cocktail Lounge), Kansas City, Mo., and Jack Tuso (an employee).**

CHARGE: Between 8–16–55 and 8–19–55, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty—by Bradley to all charges reported herein and by Tuso to dispensing *amphetamine sulfate tablets* twice.

DISPOSITION: 4–20–56. Each defendant sentenced to imprisonment for 90 days.

4873. (F. D. C. No. 38170. S. Nos. 1–689 M, 1–694 M, 1–697 M, 1–717/8 M.)

INFORMATION FILED: 10–24–55, E. Dist. S. C., against **Mrs. D. L. Skipper, t/a Skipper's Truck Stop, Summerton, S. C., and Foreman Irick and Clarence Evans (employees).**

CHARGE: Between 5–10–55 and 5–23–55, *amphetamine sulfate tablets* (counts 1 2, and 3) were dispensed 3 times and *dextro-amphetamine sulfate tablets* (counts 4 and 5) were dispensed twice without a prescription.

PLEA: Nolo contendere—by Skipper to 5 counts of information; by Irick to counts 1, 2, and 3; and by Evans to counts 4 and 5.

DISPOSITION: 1–16–56. Skipper—$300 fine or 3 months in prison; Irick and Evans—each $50 fine or 30 days in prison.

4874. (F. D. C. No. 37238. S. Nos. 65–744/8 L, 71–373 L, 71–375 L.)

INFORMATION FILED: 3–3–55, N. Dist. Ill., against **Traficante Bros. Drugs, Inc., Chicago, Ill., Emil Traficante (manager of the corporation's West Taylor Street store), Donald J. Mahoney (an apprentice pharmacist at such store), and Fred A. Granata (an apprentice pharmacist at the corporation's South California Avenue store).**

CHARGE: Between 12–1–53 and 2–15–54, *amphetamine sulfate tablets* (counts 1, 2, and 3) were dispensed 3 times and *methyltestosterone tablets* (counts 4, 5, 6, and 7) were dispensed 4 times without prescriptions.

PLEA: Nolo contendere—by corporation to 7 counts of information; by Emil Traficante to counts 1, 2, and 3; by Donald J. Mahoney to counts 4 and 5; and by Fred A. Granata to counts 6 and 7.

DISPOSITION: 5–16–55. Fine of $500, plus costs, against corporation, and fine of $250 against Emil Traficante, $100 against Donald J. Mahoney, and $100 against Fred A. Granata.

4875. (F. D. C. No. 37871. S. Nos. 60–576 L, 60–579 L, 60–598 L, 60–871 L.)

INFORMATION FILED: 9–7–55, W. Dist. S. C., against **McLeskey-Todd Drug Co.,**

Inc., Anderson, S. C., and W. Harry McLeskey (president), Harvey E. Todd (vice president), and James B. Smith (an employee of the corporation).

CHARGE: Between 7–1–54 and 9–15–54, *Nembutal Sodium capsules* (counts 2, 3, and 4) were dispensed 3 times and *Seconal Sodium capsules* (count 1) were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by corporation to each of 4 counts of information; by W. Harry McLeskey to count 1; by James B. Smith to count 2; and by Harvey E. Todd to counts 3 and 4.

DISPOSITION: 11–21–55. Corporation—$1.00 fine; McLeskey and Todd—$100 fine each; and Smith—$25 fine.

4876. (F. D. C. No. 37873. S. Nos. 60–574 L, 60–577 L, 60–588 L, 60–602 L, 60–654 L, 60–659 L, 60–877/8 L.)

INFORMATION FILED: 9–9–55, W. Dist. S. C., against **Economy Drug Co. (a partnership), Anderson, S. C., and Jack H. Wright and John W. Glenn (partners in the partnership), Paul J. High and George W. Evans (pharmacists), and William F. Kirby (an employee).**

CHARGE: Between 7–1–54 and 9–15–54, *Nembutal Sodium capsules* (counts 1, 2, 3, and 4) and *Seconal Sodium capsules* (counts 5, 6, 7, and 8) were each dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by partnership to each of 8 counts of information; by William F. Kirby to count 1; by Jack H. Wright to counts 2, 6, and 8; by Paul J. High to counts 3 and 5; by George W. Evans to count 4; and by John W. Glenn to count 7.

DISPOSITION: 10–24–55. Partnership—$1.00 fine; Wright and Glenn—$100 fine each; other individuals—$25 fine each.

4877. (F. D. C. No. 37886. S. Nos. 60–491 L, 60–498 L, 60–562 L, 60–593 L, 60–684 L, 60–779 L, 60–782 L.)

INFORMATION FILED: 7–22–55, S. Dist. Fla., against **Silver Palace Pharmacy (a partnership), Fort Pierce, Fla., and George E. Felt, Delmas E. Wallis, and William K. Nye (pharmacists).**

CHARGE: Between 5–22–54 and 8–30–54, *Seconal Sodium capsules* (counts 1, 2, and 3) and *cortisone acetate tablets* (counts 4, 5, and 7) were each dispensed 3 times and *Terramycin tablets* (count 6) were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere—by partnership to each count; by Felt to counts 1, 5, and 6; by Wallis to counts 2 and 3; and by Nye to counts 4 and 7.

DISPOSITION: 11–4–55. Partnership—$200 fine on count 1; sentence withheld on remaining counts. Fine of $50 each against Felt on count 1, Wallis on count 2, and Nye on count 4. Imposition of sentence against individuals withheld with respect to remaining counts to which individuals had pleaded.

4878. (F. D. C. No. 38513, S. Nos. 10–657/8 M, 10–662/3 M.)

INFORMATION FILED: 12–16–55, Dist. Minn., against **Gustaf Eugene Linden (manager of, and pharmacist for, Linden Rexall Drugs), St. James, Minn.**

CHARGE: Between 12–31–54 and 1–6–55, *Seconal Sodium capsules* and *Dexedrine Sulfate tablets* were each dispensed once upon requests for prescription

refills without authorization by the prescriber, and *pentobarbital sodium capsules* and *Dexedrine Spansule capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–9–56. $50 fine, sentence to imprisonment for 6 months suspended, and defendant placed on probation for 3 years.

4879. (F. D. C. No. 37221. S. Nos. 75–485/6 L, 75–564 L, 75–568/9 L.)

INFORMATION FILED: 4–5–55, E. Dist. Va., against **John Charles Garland, Jr., t/a Ideal Pharmacy, Portsmouth, Va.**

CHARGE: Between 5–27–54 and 6–17–54, *thyroid tablets* were dispensed once, *sulfadiazine tablets* were dispensed twice, and *Dexedrine Sulfate tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before a jury on 11–14–55. On the same day, the jury returned a verdict of not guilty.

4880. (F. D. C. No. 37237. S. Nos. 60–250/1 L, 60–260 L, 60–263 L, 60–484 L, 60–559 L.)

INFORMATION FILED: 3–29–55, S. Dist. Fla., against **Sanford J. Harrell (a pharmacist for Preston Drugs, Inc.), Jacksonville, Fla.**

CHARGE: Between 3–7–54 and 6–2–54, *thyroid tablets* and *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil* were each dispensed once without a prescription, and *Seconal Sodium capsules* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6–3–55. $150 fine.

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[1] (4879) Prosecution contested.
[2] (4844) Prosecution contested. Contains opinion of the court.

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